	Page 1
1	IN THE UNITED STATES DISTRICT COURT
	FOR THE NORTHERN DISTRICT OF OHIO
2	EASTERN DIVISION
3	
4	
	IN RE: NATIONAL PRESCRIPTION MDL No. 2804
5	OPIATE LITIGATION Case No. 17-md-2804
6	
-	This document relates to: Judge Dan
7	Aaron Polster
8	The County of Cuyahoga v. Purdue
0	Pharma, L.P., et al.
9	Case No. 17-OP-45005
10	City of Cleveland, Ohio vs. Purdue
11	Pharma, L.P., et al.  Case No. 18-OP-45132
12	The County of Summit, Ohio,
12	et al. v. Purdue Pharma, L.P.,
13	et al. v. ruruue rharma, h.r., et al.
13	Case No. 18-OP-45090
14	Case No. 10 01 43090
15	
16	
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18	Videotaped Deposition of Matthew Strait
19	Washington, D.C.
20	May 31, 2019
21	9:05 a.m.
22	
23	
24	Reported by: Bonnie L. Russo
25	Job No. 3404564

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Page 2
        Videotaped Deposition of Matthew Strait held
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	Jeff Swaine (Via Teleconference)
6	Daniel Russo, Videographer
	Solomon Francis, IT Specialist
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			Page 8
1		CONTENTS	
2	EXAMINATION O	F MATTHEW STRAIT	PAGE
3	BY MR. MASTER	S	13
4			113
5	BY MS. ELLIS		70
6			
7			
8		EXHIBITS	
9	Exhibit 1 N	otice of Videotaped	14
	D	eposition of Matthew Strait	
10			
	Exhibit 2 L	etter dated 5-24-19	15
11			
	Exhibit 3 R	eport to Congressional	23
12	R	equesters	
13	Exhibit 4 P	harmacist's Manual	47
14	Exhibit 5 T	estimony Before the	52
	C	committee on the	
15		udiciary, U.S. Senate	
16	Exhibit 6 L	etter dated	56
		tamped 6-9-17	
17		JS-DEA-00026731-733	
18	Exhibit 7 E	-Mail dated 2-26-18	61
		ttachment	
19		IS-DEA-00026897-902	
20		AO-15-471	65
	U	IS-DEA-00026833-834	
21			
		E-Mail dated 4-27-16	8 0
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	U	IS-DEA-00026799-803	
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		G-Mail dated 12-20-16	85
24		ttachment	
2.	U	IS-DEA-00026803-810	
25			

		Page	9
1	EXHIBITS (CONTINUED):		
2			
3	Exhibit 11 E-Mail Chain		99
	dated 2-20-14		
4	MCKMDL00538072-076		
5	Exhibit 12 E-Mail Chain		104
	dated 10-13-14		
6	CAH_MDL2804_02423059-0	64	
7			
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Page 10 PROCEEDINGS 1 2. 3 THE VIDEOGRAPHER: Good morning. We are going on the record at 9:05 4 a.m. on May 31st, 2019. 5 6 Please note that the microphones are sensitive and may pick up whispering, private conversations and cellular interference. 8 Please turn off all cell phones or place them 9 10 away from the microphones as they can interfere with the deposition audio. Audio and video 1 1 12 recording will continue to take place unless 13 all parties agree to go off the record. This is Media Unit 1 of the video 14 15 recorded deposition of Matthew Strait, taken by counsel for defendant the matter of In Re: 16 17 National Prescription Opiate, filed in the United States District Court for the Northern 18 19 District of Ohio, Eastern Division, Case No. 20 17-MD-2804. 21 This deposition is being held at Williams & Connolly, located at 725 12th 2.2 2.3 Street, Northwest, Washington, D.C. 2.4 My name is Daniel Russo from the 25 firm Veritext Legal Solutions, and I'm your

Page 11 videographer today. The court reporter is 1 Bonnie Russo from the firm Veritext Legal Solutions. 3 Counsel and all present in the room 4 and everyone attending remotely will now state 5 6 their appearances and affiliations for the record, please. MR. MASTERS: Brad Masters, Williams 8 & Connolly, for Cardinal Health. 9 10 MS. WICHT: Jennifer Wicht, Williams & Connolly, for Cardinal Health. 11 12 MR. RUIZ: Anthony Ruiz, Zuckerman 13 Spaeder, on behalf of CVS Indiana, LLC, and CVS Rx Services, Inc. 14 MS. MONAGHAN: Megan Monaghan from 15 16 Covington & Burling on behalf of McKesson. 17 MS. MACKAY: Melanie Mackay from Dechert for Purdue. 18 19 MR. PIGGINS: Michael Piggins from 20 Weitz & Luxenberg on behalf of the plaintiffs. 21 MS. ELLIS: Tiffany Ellis, Weitz & 2.2 Luxenberg, on behalf of the plaintiffs. MR. MASTERS: Yeah. Go ahead. 23 24 MR. RZODKIEWICZ: Johne Rzodkiewicz, 25 DOJ.

	Page 12
1	MR. FINKELSTEIN: David Finkelstein,
2	Department of Justice.
3	MS. SPEARS: Mariama Spears, Drug
4	Enforcement Administration.
5	MS. BACCHUS: Renee Bacchus, United
6	States Attorney's Office for the Northern
7	District of Ohio on behalf of DOJ and DEA.
8	MS. WAITES: Natalie Waites on
9	behalf of DOJ and DEA.
10	MR. STRAIT: And Matthew Strait,
11	DEA.
12	THE VIDEOGRAPHER: Can everyone
13	remotely please state their name.
14	MS. MATSOUKAS: Yes. This is
15	Kathleen Matsoukas from Barnes & Thornburg on
16	behalf of H.D. Smith.
17	MR. BARNES: Robert Barnes, Marc &
18	Marcus & Shapira on behalf of HBC Service
19	Company.
20	MR. BEISELL: Patrick Beisell from
21	Jones Day on behalf of Wal-Mart.
22	MR. SWAINE: Jeff Swaine
23	(Telephone audio malfunction.)
24	MR. HIMMEL: Brian Himmel,
25	AmerisourceBergen Drug Corporation.

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1	MR. SINDELAR: Jeff Sindelar from
2	Tucker Ellis on behalf of Johnson & Johnson and
3	Janssen Pharmaceuticals.
4	MR. WALLACE: Matt Wallace of
5	O'Melveny & Myers on behalf of Johnson &
6	Johnson and Janssen.
7	MR. LAVELLE: John Lavelle, on
8	behalf of Rite Aid of Maryland.
9	MR. STEPHENS: Neil Stephens for
10	Jones Day for Wal-Mart.
11	MS. MATIC: Kristina Matic, Foley &
12	Lardner, for Anda.
13	THE VIDEOGRAPHER: Will the court
14	reporter please swear in the witness.
15	
16	MATTHEW STRAIT,
17	being first duly sworn, to tell the
18	truth, the whole truth and nothing but the
19	truth, testified as follows:
20	
21	THE VIDEOGRAPHER: You may proceed,
22	Counsel.
23	EXAMINATION BY COUNSEL FOR CARDINAL HEALTH
24	BY MR. MASTERS:
25	Q. Good morning, Mr. Strait.

Page 14 Thank you for being here today. 1 2. Α. Good morning. Have you ever been deposed before? 3 0. No. Α. 4 This is your first time. 5 0. 6 Α. Yes. 0. So just real quick, some ground We'll try not the talk over each other 8 rules. 9 so the court reporter doesn't have too hard of 10 a time. 11 And if you have any questions about 12 my questions, feel free to ask me. 13 If -- if counsel objects, you should 14 still answer the question unless -- unless 15 you're instructed not to. Oftentimes these 16 objections are just for the record later. 17 Any question before we proceed? 18 Α. No. 19 Okay. How long have you been at the 20 Drug Enforcement Administration? 21 In August it will be 20 years. 2.2 MR. MASTERS: I'm introducing what will be marked as -- as Exhibit 1. 23 2.4 (Deposition Exhibit 1 was marked for identification.) 25

Page 15 BY MR. MASTERS: 1 2. Q. Have you seen this document before? Α. I have. 3 Do you recognize it as the notice of 4 Ο. deposition for today's deposition? Yes. 6 Α. 7 MR. MASTERS: One more housekeeping document before we get underway. 8 9 I'm showing you what has been marked 10 as Exhibit 2. (Deposition Exhibit 2 was marked for 11 12 identification.) 13 BY MR. MASTERS: 14 Ο. Can you identify this document? 15 Α. This was my authorization to 16 participate in the capacity in which I would be 17 authorized to participate today. 18 And have you seen this document Q. before? 19 20 Α. I have. 21 Okay. I'd like to direct your 2.2 attention to Page 8, the section titled Topic 21, referring to your communications relating 23 to -- relating to and efforts to comply with 24 the reports and recommendations contained in 25

Page 16 the following GAO reports. 1 2. Do you see that? 3 Α. Yes. When it says "your," you understand 4 that that is referring to the Drug Enforcement 5 Administration, correct? 6 Α. Correct. And that today testifying here, you 8 are testifying on behalf of the Drug 9 Enforcement Administration. 10 11 Α. Correct. 12 So when we -- so when I refer to 13 "you" in this deposition, unless I refer specifically to you, I'm referring to the Drug 14 Enforcement Administration, correct? 15 16 Α. Yes. 17 Do you understand that the subject 18 matter on which you are authorized to be -- to -- to testify today is -- is included here in 19 20 this section under Topic 21? 21 Α. Yes. What is your current position at the 2.2 Drug Enforcement Administration? 2.3 I am the senior policy advisor to 2.4 Α. the assistant administrator for the diversion 2.5

Page 17 control division. 1 Q. And what is your responsibility as the senior policy advisor? 3 I report directly to the assistant 4 Α. administrator and advise him on policy matters 5 that are relevant to the diversion control 6 program, the mission of the program. Okay. Prior to your current role as 8 Q. senior policy advisor, what was your role at 9 10 Drug Enforcement Administration? 11 I've had several roles over the last 12 20 years. And I can get into as much or as 13 little detail as -- as you like about those. Let's -- let's take the last let's 14 Ο. 15 say five years. 16 Okay. I've been back in the 17 diversion control program since June of 2017 18 serving in the capacity I'm in now. Prior to that, for two and a half 19 20 years prior to, I was the section chief for 21 DEA's congressional affairs section and 2.2 therefore had the liaison responsibilities for 2.3 the agency with congress. 2.4 Q. When you say "liaison

responsibilities, " can you give me a little

25

more detail about what that means?

- A. Sure. So in -- in congress's role of doing oversight over the federal government, including DEA, my roles would have been prepping witnesses for congressional testimony, providing formal or informal views on legislative proposals that affected DEA, and also working with the interagency on issues of interest in which other agencies might be testifying or working with congress on matters that impact DEA.
- Q. The Government Accountability Office is a legislative agency, correct?
  - A. Yes.
- Q. So in your role as liaison between DEA and congress, did your responsibilities intersect with the Government Accountability Office?
  - A. Yes.
- Q. Were -- would you have been aware of investigations and reports of the Government Accountability Office into the Drug Enforcement Administration?
  - A. Yes.
  - Q. And what was the nature of your role

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Page 19 as -- as a liaison in that intersection between 1 the Drug Enforcement Administration and the 3 GAO? When these GAO investigations were 4 Α. requested, they were requested by members of 5 congress. And I would not have had a role in 6 the day-to-day interactions with GAO. But following the release of those 8 9 reports, they were the subject of congressional 10 hearings that -- that ensued shortly 11 thereafter. And so that would have been my 12 role, is -- is prepping witnesses for that 13 testimony. Can you explain for the jury what 14 Ο. 15 the Government Accountability Office is? 16 MS. WAITES: Objection. Scope. And I'll just say, when I say 17 18 "scope," just to be shorthand, I'm saying it's 19 outside the scope of the 30(b)(6) designation. 20 MR. MASTERS: Sure. 21 THE WITNESS: The GAO largely is 2.2 charged with assisting congress in their oversight role. So in my times -- in many 2.3 24 instances, from -- from my experience, GAO

reports or requests come from members of

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congress as they try to understand better things that they hear from the general public.

BY MR. MASTERS:

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- Q. In your experience, how does the GAO go about its -- it's role in -- in oversight?
- A. I believe they're very methodical.

  I think they do really good work.
- Q. And -- and what kind of work do they
  -- so you mentioned earlier that members of
  congress may request the GAO to investigate
  something.

When you say "they're very methodical," what do you -- what do you mean by that?

A. Just the way they go about doing their business. The work that they do, they generally come in, have a kick-off meeting with the -- the subject of their investigation, the agency. They ask a number of very deliberative questions. They seek responses in -- in certain time frames. And there's oftentimes a very persistent exchange of information throughout their audit period.

They're very good at controlling deadlines and helping congress get their

responses in -- in a timely fashion.

- Q. When the GAO investigates let's say the Drug Enforcement Administration and issues recommendations, does the -- does -- does the DEA take those recommendations seriously?
  - A. Absolutely. Yes.
- Q. Does -- does the DEA have an obligation to respond to particular recommendations that the GAO makes?
  - A. Yes.

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- Q. Are there internal processes for addressing GAO recommendations?
  - A. Absolutely. Yes.
- Q. As a matter of course -- well, let me ask it this way: What is typical -- what are the kinds of internal processes for responding to GAO recommendations?
- A. Well, DEA has a whole GAO audit liaison team whose sole function is to ensure that GAO is getting, one, responses to their questions during the audit time frame when a --when a report is under consideration; but then also, on follow-up, once recommendations are made, our audit liaison team is consistently working with the program office to what we call

Page 22 close out a recommendation. 1 Ο. And what does it mean to close out a recommendation? 3 It means to address to the 4 Α. satisfaction of GAO the recommendations that 5 6 they've made. Now, typically when the -- when the 0. GAO investigates an issue, they will give the 8 9 agency an opportunity to respond before 10 releasing their report; is that correct? 11 That's correct. Α. 12 MS. WAITES: Objection. Vague. 13 Just make sure I... 14 BY MR. MASTERS: 15 Ο. In your experience, that is -- that 16 is true of the GAO's handling of investigations 17 relating to the DEA, correct? 18 Α. Yes. And then the GAO will -- strike 19 20 that. 21 The -- the DEA will then have an opportunity to respond, right? 2.2 2.3 Α. Yes. 24 Q. And the GAO, if there is a response, 25 will respond to the response in their report,

Page 23 right? 1 Α. GAO takes DEA's response in 3 consideration and may or may not make changes to their final report. But they generally do 4 comment in their report as to their agreement 5 or disagreement with -- with comments made by 6 the -- by the DEA. (Deposition Exhibit 3 was marked for 8 identification.) 9 10 BY MR. MASTERS: 11 I'm handing you what has been --12 hold on a second -- what has been marked as 13 Exhibit 3. 14 Can you identify this document? 15 This is the GAO's report known in 16 the -- known by GAO as GAO 15471. 17 And you -- you have seen this report before, correct? 18 19 Α. Correct. 20 When did you first become aware of Q. 21 this report? 2.2 Α. Back in 2015. 2.3 That was when the report was issued? 0. 24 Α. Yes. Were you aware of the -- of the 25 Q.

Page 24 investigation prior to the issuance of this 1 2. report? In my capacity in our congressional 3 Α. affairs office, I was aware that the -- the 4 study was being undertaken. But I was not 5 aware of when it was going to culminate, when 6 it was going to be issued. MR. MASTERS: Okay. Great. 8 9 Can we go off the record real guick 10 to address this ELMO issue. 11 THE VIDEOGRAPHER: We are going off 12 the record. 13 The time is 9:21. (A short recess was taken.) 14 THE VIDEOGRAPHER: We are going back 15 16 on the record. 17 The time is 9:24. 18 You may proceed, Counsel. BY MR. MASTERS: 19 20 Turning to Page 1 of the report --Q. 21 or I should say the -- the very first page, the 2.2 summary, the first full paragraph, the second sentence from the bottom states: "Federal 2.3 24 internal control standards call for adequate communication with stakeholders." 25

Page 25 Do you see that? 1 2. Α. Second from the bottom. I -- of the first full paragraph? 3 Yes. 4 0. Α. "Federal" -- yes. 5 Does the DEA agree with that 6 0. statement? Α. 8 Yes. 9 In this study the GAO was asked by 10 members of congress to review the adequacy of 11 DEA's communications and quidance with 12 distributors and pharmacies about their 13 regulatory responsibilities, correct? 14 And practitioners. Α. 15 Ο. Sorry. And practitioners. 16 So they were asked to look at the 17 communications and guidance between DEA and distributors, pharmacies and practitioners? 18 Correct. 19 Α. 20 And to conduct its investigation Ο. 21 into the communication and quidance with these 2.2 registrants, what did the GAO do? 2.3 Α. They did a --2.4 MS. WAITES: Objection. Vaque. 2.5 THE WITNESS: They did a survey.

They conducted a survey for each of the registrant populations.

BY MR. MASTERS:

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- Q. Was that a nationally representative survey?
- A. They called it generalizable. They interviewed -- they sent the survey out to 200 distributors, 300 pharmacies and 400 practitioners.

But for a point of consideration,

300 pharmacies, we have about 71,000 pharmacies
presently. With our practitioner community, we
have 1.7 million prescribers at present. So
they -- they did 400. And they -- they used a
statistical model to -- to make it
generalizable to the public.

- Q. And what about with distributors; how many distributors are there?
- A. 200 of -- presently -- in the report they refer to 9 -- over 900, I think 945. But on the controlled substance side, we have 750.
- Q. Okay. And same -- same with distributors as -- as with pharmacies and -- and practitioners; they used a statistical model to make it generalizable with respect to

Page 27 distributors, right? 1 Α. That's what's in their report, yes. 3 They also interviewed 26 national Ο. associations and other nonprofit organizations, 4 correct? 5 6 Α. Correct. 7 And they interviewed 16 government Q. agencies from four different states? 8 9 Α. That is correct. 10 And in addition to the web-based Ο. 11 surveys of all those registrants you mentioned, 12 the national associations and the government 13 agencies, the GAO also reached out to DEA for its perspectives on communications and guidance 14 15 to registrants, correct? 16 That is correct. Α. 17 I'd like to direct your attention to Q. 18 Page 6 of the report, the full paragraph beginning with "We also obtained." 19 20 It -- it states: "We also obtained 21 documents from and interviewed DEA Office of 2.2 Diversion Control officials who have oversight 2.3 responsibility for DEA registrants and are 2.4 engaged in addressing prescription drug abuse

and diversion issues to learn about how DEA

2.5

Page 28 interacts with its registrants and other 1 nonfederal stakeholders and to obtain DEA's perspectives on information from our survey 3 results and interviews with nonfederal 4 stakeholders." 5 Did I read that correctly? 6 Α. Yes. Is that consistent with the DEA's 8 0. understanding of GAO's engagement with DEA in 9 the course of this investigation? 10 11 Yes. Α. 12 That report indicates that the GAO Ο. 13 interviewed DEA Office of Diversion Control officials, correct? 14 15 Α. Correct. 16 Who was interviewed? Ο. 17 I don't know specifically the names Α. 18 of the individuals that were interviewed, but they would have been senior officials within 19 20 the diversion control. At the time it was the Office of 21 2.2 Diversion Control. Now they are the Diversion Control Division. 2.3 And these senior officials would 2.4 Q. have had personal knowledge and understanding 25

of the communications and guidance that DEA had given to registrants in the past, correct?

- A. Absolutely. Yes.
- Q. It also indicates that -- that GAO obtained and reviewed documents from the Drug Enforcement Administration, correct?
  - A. Yes.

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- Q. What documents did they obtain?
- A. Well, I -- I believe they were referred to throughout the report -- some of the documents -- they talked about a Know Your Customer document in 2011. And I'm not -- I'm not certain of what other types of documents they would have specifically asked for and reviewed.
- Q. One of the issues that the GAO was investigating was the adequacy of DEA's guidance to distributors relating to suspicious order monitoring, correct?
  - A. Yes.
- Q. Did the GAO issue any recommendations concerning DEA's guidance to wholesale distributors relating to suspicious order monitoring and reporting?
  - A. Let me go back to read the

Page 30 recommendation. 1 Recommendation 2 was to --2. 3 Can -- before you begin, can you let 0. me know which page you're reading from? 4 I'm on Page 44 of the report. 5 Α. 6 Ο. Okay. Great. I'm sorry. Please continue. Recommendation 2 was: "Solicit Α. 8 9 input from distributors or associations 10 representing distributors and develop 11 additional guidance for distributors regarding 12 their roles and responsibilities for suspicious 13 orders monitoring and reporting." 14 Now, in your understanding of the Ο. 15 GAO's report, that recommendation encompassed 16 both additional communications with 17 distributors and additional written guidance, 18 correct? Objection. Misstates 19 MS. WAITES: 20 the document. Mischaracterizes the document. 21 THE WITNESS: I just want to go back and read specifically. 2.2 "Solicit input and develop 2.3 additional quidance for distributors." 2.4 2.5 It doesn't necessarily, as I

understand, separate between whether it be verbal or whether it be in writing.

BY MR. MASTERS:

- Q. Okay. Did -- did the report say that some of the distributors wanted more quidance?
  - A. Yes.

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- Q. In fact, more than half of the distributors who responded to the open-ended questions in the survey said they needed more communication, information and inter -- interactions with DEA, correct?
- A. Yes. I believe that's on Page 26 of the report, if I'm not mistaken.
- Q. That is correct. You have a great memory.

In the middle of paragraph beginning with "Furthermore," it says: "Furthermore, in response to an open-ended question about what additional interactions they would find helpful to have with DEA, more than half of the distributors that offered comments said they needed more communication or information from or interactions with DEA."

Did I read that correctly?

- A. That -- that looks correct, yes.
- Q. Did the GAO say that the DEA was giving more written guidance to pharmacies and physicians than it was to distributors?
- A. I think that's a fair characterization. The report discussed the pharmacist manual and the practitioner's manual, which were written publications on the diversion web site. And there is no such manual for DEA registered distributors.
- Q. Let's -- let's go ahead and turn to that section of the report. It's one page over on Page 25.
  - A. Uh-huh.

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- Q. Would you please read for the record the first two sentences of the second paragraph.
- A. "Some survey responses indicate that additional guidance for distributors regarding suspicious orders monitoring and reporting, as well as more regular communication, would be beneficial.

For example, while DEA has created guidance manuals for pharmacists and practitioners, the agency has not developed a

Page 33 quidance manual or a comparable document for 1 distributors." Did the GAO conclude that additional 3 Ο. quidance for distributors regarding suspicious 4 order monitoring and reporting would be 5 beneficial? 6 Their recommendation is as we had previously discussed. 8 And -- and the GAO found 9 Ο. 10 specifically that that additional guidance 11 would be beneficial, correct? 12 Well, if they are making a Α. 13 recommendation, then they are recommending that the DEA take action on that front. 14 15 Q. Okay. Great. 16 And -- and just going back to Page 17 25, the first sentence indicates that -- well, I'll -- I'll strike that. 18 19 Was the GAO concerned that, in the 20 absence of clear guidance, distributors may be 21 setting conservative thresholds on the amount of controlled substances that they will sell to 2.2 2.3 pharmacies. 2.4 MS. WAITES: Objection. Vaque. Lacks foundation. 2.5

THE WITNESS: I -- I don't want to get into the head of GAO. I actually don't know the answer to your question.

## BY MR. MASTERS:

Q. Let's turn to Page 27 of the report, the second paragraph about two-thirds of the way down, beginning with "Additionally."

Do you see that?

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- Q. Can you read that sentence?
- A. "Additionally, in the absence of clear guidance from DEA, our survey data show that many distributors are setting thresholds on the amount of certain controlled substances that can be ordered by their customers, i.e., pharmacies and practitioners, which can negatively impact pharmacies and ultimately patients' access."
- Q. Does the DEA agree with that statement?
- A. I would say that this sentence is talking about what distributors told GAO. And I think that G -- we would agree that arbitrary thresholds set by a pharmacy -- or excuse me -- by a distributor could create supply access

Page 35 issues. 1 2. But on the flip side, I would say that those types of arbitrary thresholds could 3 actually create oversupplies as well. 4 And here the GAO, in -- in response 5 6 to the surveys, is observing that the thresholds are restricting supply, correct? They're quote -- I -- I take this 8 Α. 9 statement to be quoting from one of the survey 10 respondents. And it's unclear whether -- oh, 11 that was a chain pharmacy corporate office 12 survey. 13 I was going say I was unclear as to whether it was a -- a distributor or a pharmacy 14 15 that was actually indicating that. 16 So the -- so the -- the pharmacy 17 surveys are showing that -- are showing to --18 to GAO that these -- that the absence of clear 19 quidance is resulting in distributors setting 20 thresholds that are -- that's restricting the 21 supply of these drugs and ultimately negatively 2.2 impacting pharmacies and patient access, 2.3 correct? 2.4 MR. SMITH: Objection. Mischaracterizes the document. 2.5

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THE WITNESS: And I was going to say
I -- I would push back on that -- the way that
you offered that. Because I think you're
inferring that the lack of guidance has
resulted in these distributors setting
arbitrary thresholds.

That is a business decision that is being made by distributors. And so I can't necessarily say that this document connects one with the other.

## BY MR. MASTERS:

- Q. So in the GAO's view though, "In the absence of clear guidance from DEA, our survey data show that many distributors are setting thresholds on the amount of certain controlled substances that can be ordered by their customers," correct?
- A. That is a correct repeat of that sentence. But it does -- it's coming from the survey results. So it's coming from, in this case, a pharmacy or a corporate pharmacy.
- Q. And the GAO is connecting that to the absence of clear data -- or clear guidance, right?
  - A. I -- I -- I don't -- I don't

Page 37 necessarily agree with that assertion. 1 2. Q. Okay. GAO was provided -- or GAO 3 provided DEA with a draft of this particular report prior to its publication, correct? 4 Α. Correct. 5 6 Ο. And Mr. Joseph Rannazzisi responded in a letter on behalf of DEA, correct? That is --8 Α. 9 Ο. And who --10 Α. -- correct. 1 1 -- who is Joseph Rannazzisi? Q. 12 So Joseph Rannazzisi, at the time Α. 13 this report came out, was the deputy assistant administrator for the diversion control -- or 14 the Office of Diversion Control. So he would 15 16 have been the person who ran the diversion --17 the diversion control program. 18 And -- and DEA's position was that Q. 19 additional quidance was not necessary? 20 That is correct. DEA explained the Α. 21 multitude in -- of ways in which its already 2.2 communicated in this case with distributors. 2.3 And DEA's position was that the --Ο. the text of the suspicious order regulation 24

itself was sufficiently straightforward,

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Page 38 1 correct? 2. Α. It had been in place for 40 -- at the time of this publication, probably 45 3 years; and that it was well understood by our 4 DEA registrant community; and that we did not 5 6 see a -- a need to expand upon it. And -- and be -- in part because the 0. 8 DEA's position was that it was sufficiently straightforward. 9 10 I -- I think that's correct, yes. And the -- but the GAO found in its 11 Ο. 12 survey that many registrants did not feel that 13 it was well understood and, in fact, wanted more quidance, correct? 14 15 Survey respondents did show that they would like more guidance. 16 17 More than half of the distributors 18 who -- who commented on that said -- said that, 19 right? 20 Yeah. And I -- I want to make a Α. 21 point of clarification on that. 2.2 If -- if we -- if we go to Table 21, 2.3 which is something that I think is -- is 24 necessary to point out -- remember we have 750 25 controlled substance distributors at present.

The survey asked a number of questions. And then it's asked some open-ended questions. And you're obviously referring to the open-ended questions.

But like we said at the outset, they sent 200 surveys out to distributors. They received 77 responses on a question to distributors about guidance that -- that DEA provided.

And to your point, there was a portion of those 77 who asked for more guidance.

Q. Fair enough.

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The DEA also told the GAO that, short of providing arbitrary thresholds to distributors, it cannot provide more specific suspicious orders guidance because the variables that indicate a suspicious order differ among distributors and their customers, correct?

- A. Can -- can you point that out on the --
- Q. Sure. Page -- give me one second.

  It's -- it's in the -- the letter that Joseph

  Rannazzisi sent. On Page 81 of the report,

Page 40 Page 5 of the letter. 1 2. Α. Okay. Second -- or first full paragraph, 3 Ο. last sentence. 4 Would you read that for the record? 5 6 Α. Sure. 7 "Short of providing arbitrary thresholds to distributors, DEA cannot provide 8 9 more specific suspicious orders quidance as the 10 variables that indicate an order is suspicious 11 are very fact-intensive and differ from 12 distributor to distributor and from customer to 13 customer." 14 Can you explain what that means? Ο. 15 Α. Yes, I -- I can. So DEA -- we have 16 long understood that distributors would like 17 nothing more than for DEA to tell them how much 18 an average pharmacy should be able to purchase. 19 And then they could use DEA's assessment as 20 a -- to set a threshold. And that would give 21 them the opportunity to, you know, basically 2.2 say that that's a DEA-established threshold. 2.3 What we've said is, with 71,000 24 DEA-registered pharmacies and 18,000 hospitals 2.5 and 1,700 narcotic treatment programs, all of

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the types of customers that distributors sell to, we can't do that.

Because, quite frankly, the circumstances on what is appropriate for one pharmacy may be completely different than the requirements of another pharmacy. It's based on the population. It's based on the types of patients that are bringing prescriptions in to pharmacies or -- or being dispensed or administered at hospitals. It's the based on a number of different factors.

And pharmacies that are around the corner from one another may have vastly different profiles that are acceptable.

So DEA feels very strongly that that is something that only a distributor can know. Because a distributor is going to have much more of a working knowledge of who their customers are, more so than DEA.

And I would argue that, if you end up setting an arbitrary limit on how much can be distributed by -- if DEA were to do this, you could inadvertently create a shortage of a situation if that amount is not sufficient. Or on the flip side, if the -- if that number is

Page 42 too high, you could actually create overages; 1 and therefore, DEA is of the opinion that increases in availability could have the 3 unintended consequence of increasing diversion 4 and abuse. 5 6 And so DEA was not willing to provide additional quidance -- more specific suspicious order guidance than what is in the 8 9 regulation itself? 10 At the time that this letter went 11 out, that is accurate. 12 And the regulation itself defines a 13 suspicious order as an order of unusual size, deviating substantially from the normal 14 15 pattern, or an order of unusual frequency, 16 correct? 17 That's sounds correct. Α. 18 And -- and the regulation does not Ο. 19 say what an unusual size means, correct? 20 MS. WAITES: Objection. Scope. 21 THE WITNESS: It does not go on to 2.2 define any of those terms. BY MR. MASTERS: 2.3 And at the time that this letter was 2.4 Q. written, the DEA had not provided additional 25

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specific written guidance as to what unusual size, frequency or pattern means, correct?

MS. WAITES: Objection. Scope.

THE WITNESS: That is correct.

Although I want the qualify that by saying nothing as it pertains to what I think they distributors wanted, which was something in writing.

DEA was certainly increasing its liaison opportunities with the distributor community in terms of distributor conferences that we held in '13, '15 and '16; kind of one-on-one engagements through what's known as our distributor initiative, which we initiated back in 2011 and continues to this day.

And so I think, with a very limited registrant population -- they represent, what, 0.06 percent of our DEA registrant population, if not slightly less -- that the one-on-one interaction we believe in -- in a -- in a person-to-person, face-to-face environment is -- is better.

- Q. But no written -- but you mentioned no additional written guidance, correct?
  - A. At the time of this letter, no.

Page 44 Okay. In its report GAO responded 1 2. to the DEA's letter, right? Can you repeat the question. 3 Α. In -- in its report, the GAO 4 Ο. addressed what the DEA said in its letter, 5 6 correct? Α. Yes. And notwithstanding the DEA's 8 9 comments on the draft report, the GAO still 10 found that the DEA could provide additional 11 quidance to distributors, right? 12 Can you point to what -- what you're 1.3 referring to? 14 Turning to Page 44, it says: Ο. 15 "Agency comments and our evaluation." 16 Α. Yeah. 17 Q. Do you see that? 18 Α. Yes, I do. And so this is the section in which 19 Q. 20 the GAO is responding to the Department of 21 Justice's response, correct? 2.2 Α. Yes. 2.3 And on page 45, it acknowledges the -- the DEA's concerns about our second 24 recommendation to solicit input from 25

Page 45 distributors or associations representing 1 distributors and to develop additional quidance for distributors, right? 3 Α. Yes. 4 Then on page -- well, let's -- let's 5 Ο. 6 walk through some of these. 7 It goes on to say that -- to repeat what we just talked about, that short of 8 providing arbitrary thresholds to distributors, 9 10 it cannot provide more specific suspicious orders quidance, right? 1 1 12 Α. Yes. 13 Ο. The -- the GAO is summarizing the DEA's letter. 14 15 Α. The DEA's comment. That's correct. 16 Ο. And it says: "Instead, DEA 17 highlighted regulations that require 18 distributors to design and operate systems to 19 disclose suspicious orders, " right? 20 Α. Correct. Yes. And it says: "However, according to 21 Ο. 2.2 DEA's customer service plan for registrants, 2.3 DEA is responsible for developing guidance for 24 registrants regarding the CSA and its 25 regulations. And the agency was able to create

Page 46 such quidance for pharmacy and practitioner 1 registrants." Did I read that correctly? 3 Α. That is correct. 4 Turning to Page 46, that same 5 Ο. 6 paragraph toward the end, the GAO -- well, would you please read the sentence beginning with "Therefore." 8 9 Α. "Therefore, we continue to believe 10 that DEA could provide additional written 11 quidance for distributors that could be more 12 widely accessible to all distributor 13 registrants." 14 So here the GAO is not only Ο. 15 recommending additional guidance but additional written quidance, correct? 16 17 Α. Correct. 18 And the GAO had -- had found that Ο. 19 the DEA has created guidance manuals for 20 pharmacists and practitioners like doctors but not distributors, right? 21 2.2 Α. Yes. Is it true that the DEA had created 2.3 24 manuals for pharmacists and practitioners about their regulatory obligations? 25

Page 47 Α. Yes. 1 2. (Deposition Exhibit 4 was marked for identification.) 3 BY MR. MASTERS: 4 I'm showing you what has been marked 5 Ο. 6 as Exhibit 4. Why don't you keep that report close and hand. Because we'll --8 9 Α. Come back to it? -- be coming back to it. Thanks. 10 Ο. Can you identify this document? 11 12 This is DEA's pharmacist manual. Α. 13 Ο. So this is one of the -- one of the two manuals that we just spoke about that DEA 14 15 has provided to -- to registrants but not to distributors, correct? 16 17 Α. Yeah. We would not provide this to 18 distributors. But yes, we -- this is a document that is provided for the benefit of 19 20 our 71,000 retail pharmacies nationwide. 21 And if we turn to -- just after the -- the table of contents, at -- at -- let's 2.2 23 see. Where is this? Actually, just before the 24 table of contents. This is the very second 25 page of the document -- notes that: "This

Page 48 manual has been prepared by the Drug 1 Enforcement Administration Office of Diversion 2. Control as a guide to assist pharmacists in 3 their understanding of the federal Controlled 4 Substances Act and its implementing regulations 5 6 as they pertain to the pharmacy profession." 7 Did I read that correctly? That is correct. 8 Α. 9 0. And this manual is a total of --10 let's see -- 79 pages, correct? 1 1 Correct. Α. 12 And it provides additional written Q. 13 -- additional written guidance to pharmacists about how they can comply with the CSA and its 14 15 regulations in -- in the course of their 16 profession, correct? 17 MS. WAITES: Objection. Scope. 18 THE WITNESS: It is a summary 19 document of the rules and regulations 20 pertaining to DEA registrants. 21 BY MR. MASTERS: 2.2 And it explains those -- those --Ο. 2.3 those regulations and -- and gives them quidance on how to follow them in their 24 2.5 professional practice, correct?

Page 49 MS. WAITES: Objection. Scope. 1 2. BY MR. MASTERS: That's what we just read. 3 Ο. Yeah. I -- I'm -- I'm -- that's Α. 4 fine. Yes. I agree. 5 6 Okay. And is it also true that, at the time of this report, DEA had not developed a quidance manual or comparable document to the 8 9 one we just looked at for distributor 10 registrants? 11 Α. Yes. 12 Ο. And GAO here recommended that you 13 create one. MS. WAITES: Objection. 14 Mischaracterizes the document. 15 16 THE WITNESS: GAO recommended additional written guidance or additional 17 18 guidance. And that is something that is 19 currently required in order to close out this 20 remaining open recommendation. 21 BY MR. MASTERS: 2.2 And has DEA provided that to Q. 23 distributors yet? It's deliberative. We are 24 Α. actually -- as you may know, in fall of 2017, 25

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DEA -- the Department of Justice added to its unified agenda suspicious order reporting as a regulatory priority. So there will be written guidance in the form of a notice of proposed rule making published in the Federal Register. And that's an effort that was added to the unified agenda in the fall of '17.

Q. And has -- has -- as of today, what is the status of this recommendation from the GAO?

MS. WAITES: Objection.

To the extent it calls for privileged information, you cannot respond. But if you can respond without disclosing privileged information, that's fine.

THE WITNESS: I will be very careful. Because obviously, as a deliberative document, we can't talk about the details of what may or may not be in it. But it does remain under review within the executive branch.

## BY MR. MASTERS:

Q. So as of today, DEA has not provided to -- to -- to distributors the additional written guidance called for by the GAO in this

Page 51 1 report? Beyond the stuff that we've already 2. Α. 3 discussed pertaining to our continued efforts to work with registrants directly, put --4 barring that aside, yes. 5 The req -- the regulation, once 6 published, we understand from GAO, will be the basis by which this recommendation can be 8 9 closed. 10 And just to be clear, as of today, 11 the DEA has not provided the additional written 12 quidance that GAO recommended to distributors 13 as of today, correct? 14 MS. WAITES: Objection. Asked and answered. 15 16 THE WITNESS: It remains an open 17 recommendation. 18 MR. MASTERS: Okay. Could we take a 19 quick break? 20 MS. WAITES: Yes. 21 THE VIDEOGRAPHER: We are going off 2.2 the record. This is the end of Media Unit No. 1. 23 The time is 9:59. 24 2.5 (A short recess was taken.)

Page 52 THE VIDEOGRAPHER: We are back on 1 the record. This is the beginning of Media Unit 3 No. 2. 4 The time is 10:14. 5 6 You may proceed, Counsel. 7 (Deposition Exhibit 5 was marked for identification.) 8 9 BY MR. MASTERS: 10 I'm showing you what has been marked Q. Exhibit 5. 11 12 Can you identify this document? 13 Α. Yes. This is GAO 16-737T. This was congressional testimony provided by Diana 14 15 Maurer to the senate Homeland Security 16 Committee, I believe -- I'm sorry -- Committee 17 of the Judiciary. And -- and -- sorry. 18 Ο. And who is Diana Maurer? 19 20 Her title here is director for Α. 21 homeland security and justice at the GAO. 2.2 And she was providing testimony to 2.3 congress on behalf of the GAO regarding prior GAO reports and recommendations for the Drug 24 Enforcement Administration, correct? 25

Page 53 Α. Correct. 1 2. Q. Were you aware of this testimony when it was given? 3 Yes. Because DEA had a witness as 4 Α. well. 5 Okay. Did you review this report in 6 Ο. preparation for today's testimony? I did. Α. 8 9 Turning to Page 19. Ms. Maurer, on 10 behalf of the GAO, is commenting on the DEA's 11 efforts to comply with the recommendation in 12 the report we were discussing a moment ago, 13 correct? 14 Could you point to the paragraph? 15 Q. The paragraph -- the second full 16 paragraph. 17 Α. The second full paragraph. Ι 18 have --19 So beginning the sentence "In Q. 20 commenting" --21 "In commenting." Α. 2.2 Q. -- "on our report." 23 So I'll ask my question again. Ms. -- Ms. Maurer, on behalf of the 24 GAO, is commenting here on the DEA's efforts to 25

comply with the recommendation in the report we were discussing a moment ago, correct?

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Q. And it notes that: "In April 2016, DEA provided information about ongoing efforts to educate distributors about their roles and responsibilities for monitoring and reporting suspicious orders, such as their distributor conferences, and noted that it plans to host a yearly training for distributors."

Did I read that correctly?

- A. That is correct.
- Q. Would you please read the next two sentences?
- A. "However, DEA" noted -- "However" -- excuse me.

"However, DEA did not mention any plans to develop and distribute additional guidance for distributors. We continue to believe that a guidance document similar to the one offered for pharmacies and practitioners could help distributors further understand and meet their role and responsibilities under the CSA."

Q. Is it true that at that time the DEA

had not mentioned any plans to develop and distribute additional guidance for distributors?

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A. My recollection is that the correspondence that she's referring to in April 2016, we were recommending closing the recommendation based on some of the conferences that we were hosting; and that that -- we thought that that was sufficient.

And as she had stated in her testimony, and as it became understood shortly thereafter, in order to close the recommendation, we understood that we would need to be doing something in writing.

- Q. Okay. When you say as it was made clear shortly thereafter, that in order to close the recommendation, you would -- the DEA would need to provide something in writing, what are you referring to?
- A. So as we had discussed, our GAO audit liaison team had regular correspondence with GAO with the goal of closing out recommendations. And that correspondence is in writing. And it's relatively routine.

So I am recounting my review of

Page 56 those internal communications that went back 1 and forth to GAO where we had actually, on more than one occasion, sought to close this 3 recommendation based on the -- the conferences 4 that we just referenced. And it -- that's why I say it became 6 clear that they wanted something in writing. (Deposition Exhibit 6 was marked for 8 identification.) 9 10 BY MR. MASTERS: I'm showing you what has been marked 1 1 Ο. 12 as Exhibit 6. 13 Can you identify this document? Just as I had previously stated, 14 15 this is an example of the types of correspondence that DEA -- in this case this 16 17 came from our chief compliance officer, who had the O -- the GAO audit liaison team underneath 18 This would have been that -- that routine 19 her. 20 correspondence as the agency works the closeout recommendations. 21 2.2 And specifically this is called a --Q. 2.3 a -- a Drug Enforcement Administration status 24 report, correct? 2.5 Α. Yes. They are referred to as status

Page 57 1 reports. 2. Ο. And in this status report, DEA is providing an update on actions taken to address 3 the GAO's report and recommendations, correct? 4 Correct. At this time in June of 5 6 2017, none of the recommendations had been closed. 8 Q. And as you indicated a moment ago, Recommendation No. 2, which is what related to 9 10 quidance to distributors, had not been closed 11 because the GAO felt that the DEA needed to 12 provide written guidance in order to close the 13 recommendation, correct? 14 MS. WAITES: Objection. Misstates prior testimony. 15 16 THE WITNESS: So this is the -- this is -- this response on Page 2 represents the 17 18 agency's discussion about the regulatory 19 drafting efforts that it was undertaking. 20 BY MR. MASTERS: 21 Ο. My -- my question is a little 2.2 different. 2.3 You -- you mentioned a moment ago that the -- that, as of June 2017, none of the 24 recommendation had been closed. 2.5

And I -- I'm -- I'm ask -- asking if that -- well -- that that is because, in the GAO's view, the -- the DEA needed to provide written guidance, and the DEA had not done that as of this point, correct?

- A. That's -- my understanding is that the GAO did not -- declined to close out Recommendation 2 based on previous status reports.
  - Q. Got it.

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So let's turn to the DEA's response to Recommendation No. 2.

Here the DEA states that it is:

"reviewing and revising current regulations

regarding suspicious orders, which will include

guidance for distributors regarding their roles

and responsibilities for monitoring and

reporting."

Did I read that correctly?

- A. That is correct.
- Q. So in response to the GAO's recommendation to develop additional written guidance, DEA was not proposing to develop a guidance manual or comparable document to the one that exists for pharmacists and

practitioners, correct?

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- A. I think that gets a little bit at some of the predecisional stuff that I have to raise some concerns. I -- I don't really feel I can answer that question.
- Q. In -- in the DEA status report, it mentions nothing -- in this document, the DEA mentions nothing about plans to develop a guidance manual or comparable document to the pharmacist and practitioner manual, correct?
- A. A plain reading of that first sentence talks about regulations.
- Q. Instead, in order to satisfy the GAO's recommendation to develop additional written guidance, DEA planned to revise the existing suspicious order regulations, correct?

MS. WAITES: Objection to the extent it calls for privileged information.

THE WITNESS: Clearly the -- the -- the clear language says that "we are seeking to revise our regulations."

BY MR. MASTERS:

Q. And that these new regulation would include additional guidance for distributors regarding their roles and responsibilities for

monitoring and reporting, correct?

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- A. A Federal Register Notice that seeks to revise regulations on the books for 45 years would obviously have to include extensive information, which is often considered as the public considers how they want to comment. In -- in this case, the -- the public would be our DEA registered distributor.
- Q. And the distributors would have an opportunity to comment on this additional guidance, correct?
- A. Absolutely. All formal rule making takes place under notice and comment rule making procedures. So the public will absolutely have an opportunity to comment.
- Q. And that -- and given that -- and this is the first time that these regulations would be revised, correct?
  - A. Based on --

MS. WAITES: Objection. Scope.

THE WITNESS: I was going to say,
based on my understanding -- and I didn't do a
fulsome analysis of the regulatory history on
this. But my understanding is -- is that these
regs came into play somewhere between '70 and

Page 61 '73 and have not really been revised in our 1 2. regulations since that time. 3 BY MR. MASTERS: And the next sentence indicates that 4 Ο. a preliminary draft of proposed regulations has 5 been written and is pending editing, review and 6 approval by management within the diversion control division, correct? 8 9 Α. That is what it says, yes. 10 (Deposition Exhibit 7 was marked for 11 identification.) 12 BY MR. MASTERS: 13 Q. Showing you what has been marked as Exhibit 7. 14 15 Can you identify this document? 16 This appears to be another status Α. 17 update from our audit liaison folks to GAO dated February 20th, 2018. 18 So this is a -- another status 19 Q. 20 report --21 Α. Correct. 2.2 Q. -- similar to the one we just reviewed, correct? 23 2.4 Α. Yes. If -- if we turn to the second page 2.5 Q.

Page 62 of the letter, which is -- which contains DEA's 1 2. response regarding the second recommendation, it now notes that the DEA reviewed and revised 3 the current regulation regarding suspicious 4 orders, correct? 5 6 Α. Correct. 7 So before it was the DEA is Ο. reviewing and revising, and now it's in the 8 9 past tense, right? 10 Α. Correct. 11 And the -- I guess I should have Ο. 12 asked when was this letter written? 13 Α. It was written February 20th of 2018. 14 15 Ο. And as of February 20th, 2018, when 16 was the revised regulation on track to be 17 published in the Federal Register? The revision of the current 18 Α. 19 regulation regarding suspicious orders is on 20 track to be published in the Federal Register 21 by the end of the third quarter for fiscal year 2.2 2018. So that would be June 30th, 2018. And -- and what does -- what does it 2.3 Ο. 24 mean to be -- for a regulation to be published

in the Federal Register?

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Page 63

A. That means -- to us it mean a notice of proposed rule making would be ready to be published for public comment on or before that time frame.

- Q. That still has -- as of today, sitting here today, the revised regulation that the DEA indicated was on track to be published by the end of the third quarter fiscal year 2018, June 30th, still has not been published for -- in the Federal Register, correct?
- A. Yes. If -- if we go back to
  Exhibit 6, I like DEA's response. Because the
  last two or three sentences to Recommendation 2
  talks about some executive orders that present
  a, quote, potential obstacle to publication.

"These new executive branch directives may restrict the promulgation of new regulations or may delay the approval process for any new regulation. These directives include January 20th, 2017, White House memorandum and February 2nd, 2017, Office of Management and Budget memorandum."

- Q. Okay. So -- so those were potential obstacles.
  - A. Correct.

- Q. And in -- in that -- in that update, you wrote: "Absent these potential obstacles, DEA anticipates the additional review, notice, comment and final publication in the Federal Register will be completed by the end of the third quarter fiscal year 2018."
- A. I think what we were trying to say is there's a qualifier.
  - O. Sure.

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- A. If -- absent these kind of interagency or White House directives, we could do it by then. However, as -- as -- where you're going with this question, I just want to say that that is a -- a reasonable -- excuse me -- that is a cause for why there's been delays?
- Q. In -- in your next letter you don't mention any of those obstacles.
  - A. Correct.
- Q. You instead say that it's on track to be published, right?
  - A. Correct.
- Q. And in August of 2018, the DEA provided GAO with an additional update indicating that the regulation would not be

Page 65 published at the end of the third quarter 1 2. fiscal year 2018, correct? MS. WAITES: Objection. Lacks 3 foundation. 4 THE WITNESS: Yeah. I -- I would 5 6 need to see that. 7 MR. MASTERS: Sure. 8 (Deposition Exhibit 8 was marked for identification.) 9 10 BY MR. MASTERS: Showing you what has been marked as 1 1 Ο. 12 Exhibit 8. It's a -- a double-sided document. 13 The Bates stamp for this document is US-DEA 00026833, correct? 14 Correct. 15 Α. Can you identify this document? 16 Ο. 17 This is taken from the GAO's web Α. 18 site. And it represents a summary and status of reports and open recommendations. 19 20 And specifically the status report -- the status of -- that the GAO is referring 21 2.2 to here is the status of recommendations 23 relating to the 2015 report that the DEA --24 that more DEA information about registrants' controlled substances roles could improve their 25

understanding and help ensure access, correct?

A. Correct.

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- Q. At the bottom there, it appears that there is a table with the column on the left describing the recommendation and the column on the right describing the status and comments from GAO; is that correct?
  - A. Yes.
- Q. And the second recommendation, which again is the one relating to distributors, appears to cover the end of the first page and onto the second page, right?
  - A. Yes.
- Q. And at this point, the -- the GAO's web site indicates that the status of that second recommendation is open, correct?
  - A. Yes.
- Q. And in the -- in the GAO's comments, it states that: "In February 2018, DEA reported that the agency had reviewed and revised the current regulation regarding suspicious orders and that the revised draft rule was undergoing internal DEA review. DEA reported in August 2018 that they anticipated sending the draft rule to the Department of

Justice's Office of Legal Policy by the end of the first quarter of fiscal year 2019."

Did I read that correctly?

- A. That is correct.
- Q. What does it mean to send a regulation to the Department of Justice's Office of Legal Policy?
- A. As part of our -- as part of the regulatory drafting process, we always like to make sure the public knows that it is not DEA's ability to just publish something on its own. There is often -- or not often -- in every instance extensive collaboration.

That collaboration first takes place with the Department of Justice, which is our parent organization. And then there is interagency coordination that's facilitated by the Office of Management and Budget, which is OMB.

That OMB review is going to be reviews by agencies that would be involved, like the Department of Health and Human Services in the case of controlled substance regulation.

So our -- this update is indicating

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that, by the end of the first quarter, we had hoped to have that draft sent to the Department of Justice.

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- A. And specifically the Office of Legal Policy, who oversees the reg drafting efforts for all the subcomponents within the Department of Justice.
  - Q. Thank you.

And that is a step that takes place prior to final publication in the Federal Register, correct?

- A. Absolutely. It takes place prior to publication of the notice. And it takes place prior to the publication of a final rule.
- Q. So here in the August 2018 update that is being described by the GAO, the DA -- the DEA is suggesting that it is no longer on track to publish the regulation in the Federal Register by the end of the fiscal year 2018, correct?
  - A. That's correct.
- Q. In fact, now it would be not until the first quarter fiscal year 2019 that the regulation would even be delivered to the

Page 69 Office of Legal Policy, right? 1 2. Α. That's correct. Since -- since -- well, so here we 3 0. are today, the second quarter of 2019, May 4 31st. 5 6 Has the DEA sent the regulation to the Office of Legal Policy? MS. WAITES: Objection. 8 9 If it's privileged, do not respond. THE WITNESS: Yeah. I -- I -- I 10 11 don't -- that's going to get into deliberative 12 And I don't feel comfortable 13 responding to that question. BY MR. MASTERS: 14 15 Q. Okay. As of now, the second quarter 16 of 2019, May 31st, and -- and almost four years 17 after the GAO recommended that the DEA provide 18 additional written quidance to distributors, 19 has the DEA published a revised regulation in 20 the Federal Register? 21 Α. No. 2.2 Has the DEA published a guidance Q. 23 manual or comparable document to the one that 24 exists for pharmacists and practitioners? 2.5 Α. No.

	Page 70
1	MR. MASTERS: We could go off the
2	record real quick just to make sure that I
3	don't have any more questions. But I think I
4	might be done.
5	THE VIDEOGRAPHER: We are going off
6	the record.
7	The time is 10:36.
8	(A short recess was taken.)
9	THE VIDEOGRAPHER: We are back on
10	the record.
11	The time is 10:57.
12	You may proceed, Counsel.
13	MR. MASTERS: Mr. Strait, at this
14	time I have no further questions. Thank you
15	for your time.
16	THE WITNESS: Thank you.
17	EXAMINATION BY COUNSEL FOR PLAINTIFFS
18	BY MS. ELLIS:
19	Q. Good morning, Mr. Strait.
20	A. Good morning.
21	Q. My name is Tiffany Ellis. I
22	represent the plaintiffs in this case.
23	I just have a few follow-up
24	questions for you this morning.
25	A. Okay.

Q. I want you to flip to the back page of Exhibit 3, please. Well, I guess the last page, to be technical.

The first section under that -- I'm at page -- it reads "The GAO's Mission."

Could you read that for me, please.

A. Sure.

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"The Government Accountability
Office, the audit evaluation and investigative
arm of congress, exists to support congress in
meeting its constitutional responsibilities and
to help improve the performance and
accountability of the federal government for
the American people. GAO examines the use of
public funds; evaluates federal programs and
policies; and provides analyses,
recommendations and other assistance to help
congress make informed oversight, policy and
funding decisions. GAO's commitment to good
government is reflected in its core values of
accountability, integrity and reliability."

- Q. Would you agree that that's the mission of the GAO?
  - A. Yes.
  - Q. Essentially it's to -- it's the

Page 72 audit, evaluation, investigative arm of 1 congress; is that right? 3 Α. Yes. The GA -- GAO is not responsible for 4 Ο. enforcing the Controlled Substances Act, is it? 6 Α. No. Ο. And when the GAO did this report that we've been talking about today, Exhibit 3, 8 9 it wasn't looking at whether registrants were 10 in compliance with the Controlled Substances 11 Act, was it? 12 Α. No. 13 Ο. It wasn't looking at whether those registrants have reported suspicious orders to 14 the DEA? 15 16 No. Α. 17 It wasn't looking at whether Q. 18 registrants had maintained adequate suspicious 19 order monitoring systems, was it? 20 Α. No. 21 Ο. Would you agree that, whether 2.2 registrants do these things, such as report suspicious orders and maintain adequate 2.3 24 suspicious order monitoring systems, relate to whether and -- whether or how well the DEO --25

Page 73 DEA can do its job in stopping diversion? 1 2. MS. WAITES: Objection. Scope. MS. MONAGHAN: Objection to form. 3 BY MS. ELLIS: 4 I'd like to direct you to Page 77 of 5 Ο. the report, Exhibit 3, and No. 1 of the letter 6 there. 8 Could you read the first sentence of 9 that paragraph, please. 10 Of recommend -- of the first comment 11 that DEA made or the first sentence of the 12 first paragraph? 13 I'm looking specifically at Page 77, Q. the letter to Linda Kohn dated May 25th, 14 2015 --15 16 Uh-huh. Α. 17 -- following "With respect to the G" Q. 18 -- "GAO report, DEA wishes to emphasize the following important facts." 19 20 Α. Yep. Okay. 21 And read No. 1? 2.2 Q. Yes, please. DEA's Office of Diversion Control is 23 24 responsible for administering and enforcing the 25 provisions of the CSA as they pertain to

Page 74 ensuring the availability of controlled 1 2. substances for legitimate uses while preventing their availability for diversion. The office 3 is not charged with reducing the illicit demand 4 for controlled substances." 5 6 Would you agree that that's the 7 responsibility of the DEA's Office of Diversion Control? 8 9 MS. MONAGHAN: Object to form. 10 THE WITNESS: Yes. 11 BY MS. ELLIS: 12 What is the role of the DEA? Q. 13 MS. WAITES: Objection. Vaque. Scope. 14 15 MS. MONAGHAN: Object to form. 16 BY MS. FLITS: 17 Let me direct you to Page 67 of the Q. report, Exhibit 3. 18 19 Α. Sorry. What page? 20 Page 67. Q. 21 Α. Okay. 2.2 Q. I may have the may -- wrong reference here. 23 But would you agree that the DEA's 24 25 role is the -- is the primary agency

Page 75 responsible for coordinating the drug 1 enforcement activities of the United States? 2. Α. As it pertains to pharmaceutical 3 drugs containing controlled substances, yes. 4 It's a law enforcement agency? 5 Q. 6 Α. It is. Can the DEA take administrative Ο. enforcement actions against registrants? 8 9 MS. WAITES: Objection. 10 MR. MASTERS: Objection. Scope. 11 MS. WAITES: Scope. 12 MS. MONAGHAN: Object to form. 13 THE WITNESS: Yes. 14 BY MS. ELLIS: 15 Ο. You were asked some questions 16 earlier about the difference between pharmacies 17 and distributors. I want to direct your 18 attention back to that portion of your testimony. 19 20 Do you recall? 21 Α. Yes. 2.2 Do you know how many registrants Ο. there are total? 2.3 Currently we have 1.815 million 24 Α. 25 registrants.

Page 76 Do you know how many of those are 1 2. pharmacies? Approximately 71,000. 3 Α. Do you know how many of those are Ο. 4 distributors? 6 Α. Right now -- I think I said 750, but it might be 715. But it is somewhere between 715 and 750. 8 9 715 to 750 distributors and 71,000 Ο. pharmacies. 10 Does the number of distributors 11 12 versus the number of pharmacies affect the way 13 the DEA communicates with each of those different groups of registrants at all? 14 15 MS. WAITES: Objection. Scope. 16 MR. MASTERS: Objection. Form. 17 THE WITNESS: Yes. 18 BY MS. ELLIS: 19 0. How so? 20 Obviously, with a -- with 1.8 Α. million registrants, DEA has limited resources, 21 2.2 and it does need to think about how best to 23 prioritize those resources. With our -- that portion of our drug 2.4 supply chain that handle the largest volumes of 25

Page 77 controlled substances, i.e., our manufacturers 1 2. and our distributors, our engagement with them tends to be more in person, one-on-one, and --3 and very much routine in terms of the frequency 4 by which we conduct audits and inspections of 5 6 those registrants. 7 And because of sheer numbers, our quidance to those other portions of our 8 9 registrant community that are larger, i.e., 10 pharmacies, and prescribers, we do have to rely 11 more on providing them guidance on our 12 diversion control web site. And of course we 13 do still engage with them in person by offering all sorts of different training opportunities. 14 15 So larger numbers of registrants require greater efforts? 16 17 MS. MONAGHAN: Objection. 18 MS. WAITES: Objection. Scope. 19 MS. MONAGHAN: Object to form. 20 MS. ELLIS: Let's me rephrase. 21 BY MS. ELLIS: 2.2 Q. Let -- let's go to the -- Page 2, 2.3 the summary, I guess, of Exhibit 3. What GAO recommends, this first 2.4 sentence on the bottom-left corner: 2.5

Page 78 recommends that DEA takes three actions to 1 2. improve communication with" a -- "with and 3 guidance for registrants about their CSA roles and responsibilities." 4 Sorry. Did you say page --5 Α. The summary page. 6 Ο. Α. Oh, the summary page. 8 Q. Yes. 9 Α. Okay. And I'm sorry. Where was that directive? 10 11 Just what GAO recommends. Q. 12 Α. Oh, yes. 13 Ο. You would agree that this report is focused on quidance for registrants about their 14 15 CSA roles and responsibilities, correct? 16 Α. Yes. 17 And your testimony today has been Q. focused on this report, right? 18 19 Α. Correct. 20 Is the nature of the responsibility Q. 21 for pharmacies different than that for 2.2 distributors under the CSA? 23 MS. WAITES: Object to form. Scope. 2.4 MS. MONAGHAN: Objection. Scope. MS. WAITES: Calls for legal 2.5

Page 79 conclusion. 1 2. BY MS. ELLIS: Are you aware if -- are you aware if 3 0. pharmacies and distributors are subject to 4 different regulations under the CSA? 5 6 MS. MONAGHAN: Object to form. 7 MS. WAITES: Objection. Scope. 8 Calls for legal conclusion. 9 THE WITNESS: Yes. 10 BY MS. ELLIS: Are you aware whether pharmacies 11 Ο. 12 have different reporting requirements to the 13 DEA than distributors? MS. MONAGHAN: Object to form. 14 15 Calls for legal conclusion. Scope. 16 MS. WAITES: Object to scope. 17 THE WITNESS: I am familiar with the 18 fact that all registrant classes have different 19 requirements in terms of reporting and 20 recordkeeping. So the requirements on one class of registrants, i.e., distributors, is 21 different than the requirements for another 2.2 23 class, pharmacies. 2.4 MS. ELLIS: Earlier you discussed 25 some of the things that the DEA -- some of the

Page 80 actions that the DEA had taken in response to 1 2. the GAO's report. I want to ask you some additional questions about what the DEA -- DEA 3 had done after this report at -- was issued. 4 I'm marking for the record 5 Exhibit 9. 6 7 (Deposition Exhibit 9 was marked for identification.) 8 9 MS. WAITES: Do you have a copy for 10 me? 11 MS. ELLIS: I'm sorry. I think I 12 just handed the other two down that way. I 13 apologize. BY MS. ELLIS: 14 15 Exhibit 9 is a e-mail that I believe 16 you reviewed in advance of today's deposition. 17 The Bates number is cut off a little at the 18 bottom, but for the record it's US-DEA-00026799. 19 20 Do you recall reviewing this 21 document? 2.2 Α. Yes. 23 On the second page of the document, it appears to be a letter. 24 What is this letter? 2.5

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A. This would have been one of the status update letters from our GAO audit liaison section to GAO. And this one was dated April 27th, 2016, which means that it would have been very -- within a year or right around a year after the report came out.

- Q. Is this the first status update letter that you're aware was issued following the report?
- A. No. Actually, the -- there is a reference to the -- in the first paragraph to a status response congressional letter dated September 21st, 2015.

And what that means to me is that congress probably wrote to ask about the status. And in DEA's response to congress, it would have sent a CC copy to GAO.

- Q. So that -- that would have been different than this type of letter?
- A. Correct. But it could have been similar.
- Q. Similar but not directly to GAO.

  Okay. I want to direct you to the next page of the document, Section 2.

What is your understanding of the

Page 82 DEA response in Section 2? 1 2. What is this in response to? Page 2, this is DEA's response to 3 Α. Recommendation 2 about quidance for -- for 4 distributors and those associations 5 6 representing distributors on their suspicious order monitoring reporting obligations. You were asked a lot of questions 8 Q. this morning about whether the DE -- DEA had 9 10 issued any written guidance to distributors 11 between the time that the report was issued and 12 today. 13 Does this section describe other actions that the DEA took to educate 14 15 distributors about their responsibilities under 16 the CSA? 17 Α. Yes. 18 And what are some of the actions Ο. 19 that the DEA took during this time frame as 20 outlined in this letter? 21 So the first paragraph talks about 2.2 DEA's distributor conference, which it held in 2.3 2013, and then, as indicated here, held in 2015 and 2016. 2.4

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The -- obviously what we go on to

say is that information provided during these conferences are published on DEA's web site.

The third paragraph talks about

DEA's work with the National Association of

Boards of Pharmacy and a number of other

stakeholder groups, which includes some

associations representing various aspects of

our registrant population on a consensus

document entitled "Stakeholders, Challenges and

Red-Flag Warning Signs Related to Prescribing

and Dispensing of Controlled Substances."

- Q. Were all of these efforts by the DEA to comply with the GAO's recommendation to provide distributors further guidance under the CSA?
  - A. Yes.

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- Q. Were some of these written?
- A. To the extent that the distributor conference presentations were -- are generally PowerPoint presentations and therefore are -- are written documents, yes.

And the -- the NABP document, I actually did take a look at that. I did not see where DEA was actually noted as an author, which is the reason I didn't mention it during

my -- my remarks earlier. So that I'm -- I'm not certain I can say with certainty that that would have constituted written DEA guidance.

Q. You mentioned, I think, in your earlier answer something about a distributor initiative and working directly with distributors.

Do you recall that testimony?

A. Absolutely. Yes.

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- Q. Would -- would this be a part of that?
- A. So actually the distributor initiative is separate from the issues that are outlined in this response. But certainly DEA has indicated that one of the main ways in which it interacts with the distributor community is through what's called the distributor initiative, which I believe began in 2006.

And this is direct, one-on-one engagement with DEA registered distributors.

And that's different from the distributor conference, which is a -- a number of DEA registered distributors coming to a venue free of charge, you know, to -- to receive

Page 85 presentations from DEA and to collaborate with 1 2. DEA on -- on issues. MS. ELLIS: Now marking for the 3 record Exhibit 10. US-DEA-00 -- I'm sorry. 4 US-DEA-00026803. 5 (Deposition Exhibit 10 was marked 6 for identification.) BY MS. ELLIS: 8 9 Ο. Is this also a document that you reviewed in preparation for today's testimony? 10 11 It is. Α. 12 And this is dated December 20th, Ο. 13 2016? Correct. 14 Α. 15 Ο. What is this e-mail and its 16 attachment? 17 This document actually -- the e-mail 18 that's on the front page would have been from 19 the GAO audit liaison team sending what is an 20 update memorandum to our counterparts over at 21 GAO. So is this an -- a subsequent update 2.2 23 to the one that we just discussed? Correct. In fact, on the first 24 Α. paragraph, it said "DEA provided its previous 25

Page 86 status response on April 27th, 2016. 1 that's what this Exhibit 9 was. And what is the date of the letter 3 0. attached to that e-mail? 4 It's December 20th, 2016. 5 6 Ο. I'll direct you to the second page of the letter under Heading 2. 8 Is this an additional update as to 9 what the DEA was doing in response to the GAA 10 -- GAO's recommendation that the DEA provide more specific quidance to distributors with 11 12 respect to their roles and responsibilities for 13 suspicious order monitoring? This would have included 14 Α. Yes. things that the agency was doing in an attempt, 15 16 and as the last paragraph reads, based on 17 the -- the preceding three paragraphs, 18 requesting closure of the recommendation, based 19 on this -- the preceding information. 20 And I forgot to ask you. Q. 21 In that previous Exhibit 9, did the 2.2 DEA also request closure of the recommendation? It did. 2.3 Α.

Q. Did the DEA feel at that time it had done -- did the DEA -- strike that.

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Why did the DEA request closure of the recommendation in Exhibit 9 or at the time of Exhibit 9?

- A. DEA reported in its response that it: "request closure of this recommendation based upon DEA's actions to obtain input from distributors and associations representing distributors. DEA will continue collaborating with these businesses and associations through regularly scheduled conferences and by working with NABP and the coalition of stakeholders to provide ongoing guidance to distributors regarding their roles and responsibilities for monitoring and reporting suspicious orders."
- Q. And you were just reading from the document, Exhibit 9, right?
  - A. Correct.

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- Q. Now, in Exhibit 10, did the DEA also request closure of this recommendation?
  - A. It -- it did -- or we did, yes.
- Q. What did -- what did you base that request on?
- A. It actually looks very similar to the -- to the preceding update. So we -- I'll read it for the benefit of the group.

"DEA requests closure of this recommendation based upon DEA's actions to obtain input from distributors and associations representing distributors. DEA will continue collaborating with these businesses and associations through regularly scheduled conferences and provide ongoing guidance to distributors regarding their roles and responsibilities for monitoring and reporting suspicious orders."

- Q. In addition to the efforts described in Exhibit 9, it appears that, in the third paragraph of Exhibit 10, beginning with "DEA has continued to work with distributors," there is the description of two additional conferences in 2016; is that right?
  - A. Correct.

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- Q. Could you read that aloud for the jury, please.
  - A. Sure.

"DEA has continued its work with distributors and associations by meeting with industry upon request and providing guidance and discussion related to suspicious orders.

DEA held two distributors and one reverse

distributors conference in 2016. These conferences provided DEA with an excellent opportunity to engage its distributor registrants, attachment 4, about their roles and responsibilities for monitoring and reporting suspicious orders. DEA plans to host yearly training for distributors and reverse distributors, which will answer questions on these issues."

- Q. I want to direct you to Table 21 that you discussed earlier in Exhibit 3. And that is on page --
  - A. 66?
  - Q. -- 66 -- thank you -- of the report.

In your earlier testimony, I believe you made the -- you clarified to say that the GAO's recommendation, as you understood it, was based on the response outlined in this table; is that right?

- A. Yes. And some -- and some of the -the -- they had an open-ended question, and
  then they had objective measures. And Table 21
  was representing answers to objective measures
  in their survey.
  - Q. And in Table 21, this reflects that

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there were 77 total responses from distributors; is that right?

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- A. Yes. I see one other thing that -on this table representing distributors saying
  that there may have been 78 responses. But
  yes, 77 or 78 of the 200 that were -- that
  received the opportunity to respond to their
  survey.
- Q. And you said a few moments ago that there's between, now, 715 to 750 distributors.

Was that number different at the time that this report was issued?

A. Yeah. The -- the number that's used in the report is I believe 954. And I believe the distinction there -- because I didn't go back and look at where we were in 2014. But I believe the difference is I'm talking about controlled substance distributors.

We also have a population of registrants that are involved in the distribution of List I chemicals. So I'm excluding the List I chemical population from my numbers.

Q. Would the number -- what would the number of controlled substances distributors

Page 91 have been around the time that this report was 1 2. issued, if you know? I think it would have been 3 Α. comparable to what -- the numbers that we have 4 I don't think we've seen any drastic 5 6 changes in the size of our registrant population for DEA-registered distributors. So directing your attention back to 8 Q. 9 Table 1. 10 Of those that responded to the 11 survey -- let's look at this first line here. 12 Here you see the 77 responses, 13 correct, is in respect to the DEA's Know Your Customer quidance, right? 14 15 Α. Yes. 16 Okay. And what is the total number Ο. 17 of distributors that they said -- that thought 18 that the DEA's feedback was very or moderately 19 helpful? 20 Α. So it's about two --21 MS. MONAGHAN: Object to form. 2.2 THE WITNESS: It's approximately 2.3 two-thirds of the registrants that did respond 24 to this question indicated that they found 25 DEA's guidance to be very or moderately

Page 92 helpful. 1 BY MS. ELLIS: 2. 3 A majority. Q. A majority, yes. 4 Α. And how many, according to this 5 Q. chart, found that it was only slightly or not 6 helpful at all? MR. MASTERS: Object to form. 8 9 MS. MONAGHAN: Object to form. 10 THE WITNESS: The number here is 28 11 of 77. 12 BY MS. ELLIS: 13 Q. I want to direct your attention to Page 6 of Exhibit 3. 14 15 Earlier I believe you read for the 16 record the sentence starting the second 17 paragraph with "We also obtained documents from"? 18 19 Α. Yes. 20 Were -- were you personally involved Q. in that process? 21 2.2 Α. No. 23 Are you -- and I believe you 24 testified that you're not aware of who at the DEA was involved in that process? 25

- A. That is correct. I'm not aware.
- Q. Do you know what occurred during that meeting as far as the feedback that was solicited from the DEA by the GAO?
- A. There were probably multiple meetings. But I'm not familiar with what transpired during each of those meetings.
- Q. Do you know if the DEA had any feedback into who would -- who the participants in the survey would be?

MS. MONAGHAN: Object to form.

THE WITNESS: I have reason to believe that the people who would have been involved are no longer with the agency. So I -- I don't really have a good way of trying to reconcile that.

BY MS. ELLIS:

- Q. So you don't know if the DEA had input into who the participants in the survey were?
  - A. Oh.

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MS. MONAGHAN: Objection. Form.

THE WITNESS: I do believe we had input as to who would be participating in those meetings, yes.

Page 94 BY MS. ELLIS: 1 2. Q. Do you know if the DEA had input into what the survey questions would be? 3 No. We did not have access to the 4 Α. questions. 5 Do you know if the DEA had input 6 Ο. into which states would be selected for participation in the survey? 8 MS. MONAGHAN: Object to form. 9 10 THE WITNESS: I don't know the 11 answer to that question. 12 BY MS. ELLIS: 13 Q. Do you know of anyone at the DEA who -- who would know the answer to that 14 15 question besides you? 16 I believe the people who would know, 17 like I said previously, have since retired. So I don't -- I don't know of anybody. 18 19 Do you know when the DEA first 20 learned that the GAO was working on this 21 report? 2.2 A. Go back and see if I can find it in 23 the -- I'm sorry. I don't know the answer to 24 that question. 25 Q. Are you aware of whether the GA

Page 95 [sic] solicited input from registrants into the 1 2. content of the survey? 3 MS. MONAGHAN: Object to form. THE WITNESS: I don't know the 4 answer to that question, no. 5 BY MS. ELLIS: 6 7 Q. Would that surprise you? MR. MASTERS: Objection. 8 9 THE WITNESS: Yes. That would 10 probably surprise me a little bit. 11 BY MS. ELLIS: 12 Are you aware that the GAO solicited Ο. input into this report and the survey as early 13 as July of 2013 --14 15 MS. MONAGHAN: Object to form. 16 MR. MASTERS: Object to form. 17 BY MS. ELLIS: 18 -- from registrants? Q. 19 Can you repeat that. Α. 20 Are you aware that the GAO solicited Q. 21 input into the survey and report from 2.2 registrants as early as July of 2013? MS. WAITES: Objection. Foundation. 23 24 MR. MASTERS: Objection. Scope. 25 Objection. Form.

Page 96 THE WITNESS: And the answer is no. 1 2. BY MS. ELLIS: 3 Are you aware that in August of 2013 Q. the GAO participated in a conference call with 4 the HDMA staff regarding this report? 5 6 MS. WAITES: Objection. Foundation. 7 MR. MASTERS: Objection. Scope. 8 Objection. Form. 9 THE WITNESS: No. I am not aware. 10 BY MS. ELLIS: 11 What is the HDMA; do you know? Q. 12 MS. WAITES: Objection. Scope. 13 MS. MONAGHAN: Objection. Scope and form. 14 15 THE WITNESS: HDMA is now HDA. And 16 I believe they're the Healthcare Distributor 17 Alliance. 18 BY MS. ELLIS: 19 Are you aware that this report by 20 the GEO -- GAO -- pardon me -- incorporated the 21 feedback from certain industry associations? 2.2 MS. WAITES: Objection. Foundation. 23 MS. MONAGHAN: Objection. Form and 24 foundation and scope. MR. MASTERS: Objection. Vaque. 25

Page 97 THE WITNESS: Can -- can you repeat 1 2. that question. BY MS. ELLIS: 3 Yes. We'll just go to the document. Q. 4 Let's go back to the summary page in 5 6 Exhibit 3. It's the second page of the document. The last sentence on the left-hand 8 side says: "The" GEO [sic] "administered 9 10 nationally representative web-based surveys to 11 DEA-registered distributors, individual 12 pharmacies, chain pharmacy corporate offices, 13 and practitioners. GAO also interviewed officials from DEA. 26 national associations 14 15 and other nonprofits and 16 government agencies in four states." 16 17 You see that. 18 Α. Yes, I do. Are you aware of which associations 19 20 and nonprofits those were? 21 I believe they were listed as 2.2 potential -- oh, no, they weren't listed. So I don't know which -- which associations. 2.3 2.4 So you don't to know if the HDMA or Q. 25 now called the HDA was one of the participants

Page 98 in the study? 1 MS. MONAGHAN: Object to form and foundation. 3 THE WITNESS: I don't know. But I 4 had reason to believe that they certainly would 5 have been one of the associations. 6 7 BY MS. ELLIS: Why is that? 8 Q. 9 MS. MONAGHAN: Object to form. 10 THE WITNESS: HDA represents 11 manufacturers and distributors of controlled 12 substances. They are obviously an important 13 association that we need to be working with. 14 And during my time as the head of 15 our congressional affairs section, I -- I knew 16 that they were on Capital Hill talking 17 extensively to members of congress about their representatives' concerns over the amount of 18 19 communication that they had with DEA. 20 BY MS. ELLIS: 21 You said they were on the hill Ο. 2.2 talking about their representatives' concern over the amount of communication that they had 2.3 with the DEA. 24 2.5 What do you mean?

Page 99 MS. MONAGHAN: Object to form. 1 2. Scope. THE WITNESS: So HDMA, HDA is a --3 is a lobbying firm that represents the 4 interests of -- of their clients on Capital 5 6 And they were very vocal. And they've actually testified alongside DEA witnesses at hearings in which these -- these issues were 8 brought up in terms of communication with the 9 10 agency. 11 BY MS. ELLIS: 12 Do you understand that they've tried 13 to influence the way the DEA communicates with registrants? 14 15 MR. MASTERS: Object to form. 16 Object to scope and foundation. 17 MS. WAITES: Object to scope and foundation. 18 THE WITNESS: Yes. 19 20 (Deposition Exhibit 11 was marked 21 for identification.) 2.2 BY MS. ELLIS: 2.3 I'm handing you, for the record, Ο. what's been marked as Exhibit 11, Bates 24 25 numbered page MCKMMDL 00538072.

What is the subject line of the e-mail that you have in front of you?

- A. "Inquiry from Government

  Accountability Office Regarding Distributor

  Interaction With DEA."
- Q. Could you read the first sentence of the second paragraph, please.
- A. "In August 2013, HDMA staff participated in a conference call with the GAO team tasked with pulling this report together. During this" -- I'm sorry.

Did you say --

Q. You can go on.

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- A. "During this meeting, HDMA staff gave a general overview of the industry's efforts to prevent diversion." At that -- "At the time we furnished them with testimony we provided to the Energy and Commerce Committee as well as the list of questions we had submitted DEA seeking further clarity on suspicious order monitoring and due diligence protocols."
- Q. The next paragraph starts with "Specific follow-up questions from the" GE -- "GAO."

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Page 101

Could you read that, please, for the jury.

- "We are preparing the survey Α. questionnaire now and planning our sampling methodology and have a couple of questions we'd like your input on. A, if an individual DEA-registered distributor location received our survey, how likely would they be willing and able to complete it? We have heard, for example, that chain drug stores would likely not want their individual stores to respond to our survey. Instead they prefer (insist on) sending one corporate response. B, do the individually registered locations have direct interaction with DEA and/or other federal agencies; or is that more likely to happen at the corporate level?"
- Q. And who is on the To line of this e-mail there at the top?
- A. I see a representative from

  AmerisourceBergen, a individual from Cardinal

  Health, individual from Smith Drug, another

  Cardinal Health individual, somebody from

  Mutual Drug, somebody from HD Smith, somebody

  from McKesson, and another individual from

Page 102 AmerisourceBergen. 1 2. Q. Are the companies that you just named, are you aware that those are registrants 3 of the DEA? 4 Α. Yes. 5 6 MS. WAITES: Objection. Scope. 7 THE WITNESS: Yes. BY MS. ELLIS: 8 9 Ο. And who's the From line there on 10 that e-mail? 11 It is from Pat Kelly, who is with Α. 12 HDA. 13 Ο. And what's the date on that e-mail? 14 February 20th, 2014. Α. 15 Are you aware if the DEA was asked Q. 16 for input on these questions around February 17 20th, 2014? 18 Α. I am --19 MS. MONAGHAN: Object to form. 20 THE WITNESS: I am not aware. 21 BY MS. ELLIS: 2.2 Q. Do you know if they were? I don't know. 23 Α. You mentioned earlier what the DEA 24 Q. probably would have a series of conversations 25

Page 103 with the GA -- GAO about this survey and the 1 2. report, correct? Α. Yes. 3 But you don't know when the dates of 4 those would have been? 5 No. And I -- I imagine that those 6 conversations would have been through the audit liaison section, which would have not really 8 9 been part of my involvement at the time. 10 Was the DEA invited to be at any of 11 the meetings where the GAO solicited input from 12 industry representatives? 13 MR. MASTERS: Objection. Foundation. 14 15 THE WITNESS: I don't know. 16 BY MS. ELLIS: 17 Was the G -- was the DEA privy to Q. 18 the attendee list of any of the industry 19 representatives that were participants in these 20 meeting with the GAO? 21 MR. MASTERS: Objection. Form. 2.2 Foundation. 2.3 THE WITNESS: My understanding is 24 that DEA provided access to the CSA registration database. And that's the basis by 25

Page 104 which GAO decided what their generalizable 1 sample would be for purposes of administering 3 the survey. BY MS. ELLIS: 4 Ο. So the entire database? 5 6 Α. Correct. Not necessarily -- that would not be Ο. the specific list of who participated in the 8 9 discussions with the GAO, correct? 10 MS. MONAGHAN: Object to form. 11 THE WITNESS: I -- I don't know the 12 answer to that. 13 BY MS. ELLIS: 14 0. Do you know who Rob Giacalone is? 15 Α. No, I don't. 16 (Deposition Exhibit 12 was marked 17 for identification.) 18 BY MS. ELLIS: Handing you what's been marked for 19 20 the record as Exhibit 12. 21 Are you aware that the GAO held a 2.2 meeting with industry representatives, including CSA, registrants in October of 2014? 23 2.4 MS. MONAGHAN: Object to form and foundation. 25

Page 105 THE WITNESS: I am not, no. 1 2. BY MS. ELLIS: Would you read the first two 3 0. sentences of the top of that e-mail for me, 4 5 please. Starting with "I'll ask Carl"? 6 Α. Q. Yes. "I'll ask Carl. As to HDMA, here 8 Α. are my thoughts." 9 10 Keep going. Yes, please. 11 Q. 12 Okay. "First, in my discussions Α. 13 with HDMA, they have told me that they were involved in helping to create the survey. So 14 15 I'm assuming they have already provided their input to the GAO. Second, not sure if this 16 17 meeting at NASCSA is just for industry (and not 18 trade groups) given it's targeted specifically 19 towards industry representatives. I can ask 20 HDMA if they are going/got an invitation." 21 Keep going? 2.2 Q. Sure. Go ahead. 2.3 "Lastly, not sure we want Linden 24 there at this event if we're trying to keep a 25 low profile (and not sure he can go without

Page 106 specifying for whom he is attending)." 1 2. Keep reading? Just qo ahead and --3 0. Α. Okay. 4 -- read the next two sentences. 5 Ο. 6 Α. "My overall concern with this is that we got burned before with the GAO. 8 I'm not sure how much we want to be perceived as being on the front end with them. I think 9 we've worked towards coordinating a common 10 theme from our industry colleagues (via our 1 1 12 work groups, Purdue, et cetera. Just not sure 13 the downside of the potentially irritating DEA is worth the added benefit of showing up at 14 15 this meeting where DEA reps most likely will be present at the NASCSA meeting. If you think 16 other" -- "otherwise, let's decide who should 17 qo. Thanks, Bob." 18 19 Do you know if DEA reps were present 20 at that NASCSA meeting? 21 MS. WAITES: Objection. Scope. 2.2 MS. MONAGHAN: Objection. Foundation and form. 2.3 THE WITNESS: I don't. I don't know 24 25 the answer.

		Page 107
1		BY MS. ELLIS:
2	Q.	Do you know whether there was any
3	concerted	effort by registrants to influence
4	the GAO's	report?
5		MR. MASTERS: Objection. Form.
6	Foundation	n. Scope.
7		MS. WAITES: Objection. Calls for
8	speculation.	
9		THE WITNESS: I don't know.
10		BY MS. ELLIS:
11	Q.	I want to direct your attention to
12	Exhibit 8.	
13	Α.	Was this was this part of Exhibit
14	12?	
15	Q.	It was.
16	Α.	Okay.
17	Q.	It's an attachment to the e-mail.
18	Thank you.	
19		You discussed this exhibit earlier
20	on the rec	cord.
21		Do you recall?
22	Α.	Yes.
23	Q.	And what was what is this again?
24	А.	This is a GAO summary. It's
25	available	on their web site. And it talks

about the -- the summary of the GAO report and then the status of recommendations. In this case, for this particular report, there were three recommendations. So below is the recommendation -- the three recommendations and their status.

- Q. Recommendation 2, which we discussed in depth today, was for the DEA to provide more guidance to registrations -- or registrants and associations representing registrants regarding their roles and responsibilities for suspicious order monitoring, correct?
  - A. Yes. Yes.

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Q. Back on the first page.

(Phone interruption.)

MS. ELLIS: I think we have -- you may want to mute your phone on the conference line.

(Discussion held off the stenographic record.)

MS. ELLIS: Can we go off the record for just one moment, please.

THE VIDEOGRAPHER: We are going off the record.

This is the end of Media Unit No. 2.

Page 109 The time is 11:43. 1 2. (A short recess was taken.) THE VIDEOGRAPHER: We are going back 3 on the record. 4 This is the start of Media Unit No. 5 6 3. 7 The time is 11:44. You may proceed, Counsel. 8 9 BY MS. ELLIS: We were just discussing Exhibit 8, 10 11 which is the GAO summary available on their web 12 site regarding the GAO report we've been 13 discussing today. 14 I would like to direct your 15 attention to midway through the first 16 paragraph. And there is a sentence there 17 starting with "Of those." 18 Do you see it? 19 Α. Yes. 20 Could you read that aloud, please. Q. 21 "Of those registrants that have 2.2 interacted with DEA, most were generally satisfied with those interactions. 2.3 24 example, 92 percent of distributors that communicated with DEA field office staff found 25

Page 110 them 'very' or 'moderately' helpful. 1 some distributors, individual pharmacies and chain pharmacy corporate office want improved 3 quidance from and additional communication with 4 DEA about their CSA roles and responsibilities. 5 6 For example, 36 of 55 distributors commented that more communication or information from or interactions with DEA would be helpful. 8 9 officials indicated that they do not believe 10 there is a need for more registrant guidance or 11 communication." 12 Ο. Do you understand that sentence to 13 be the support for the GAO's Recommendation 2 in that report? 14 15 Α. The --16 MR. MASTERS: Objection. 17 THE WITNESS: The 36 of 55? 18 MS. ELLIS: Yes. 19 THE WITNESS: I don't have a way of 20 knowing what GAO was thinking in terms of 21 crafting their recommendations. So I can't 2.2 answer your question. BY MS. ELLIS: 2.3

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If you could read that aloud, please.

Let's look at the second paragraph.

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Q.

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A. "Officials GAO interviewed from 14 of 16 state government agencies and 24 of 26 national associations said they interact with DEA through various methods. 13 of 14 state agencies and 10 of 17 national associations that commented about their satisfaction with DEA interactions said they were generally satisfied. However, some associations wanted improved DEA communication."

Q. The next paragraph goes on to put a number on that, quote, some associations, doesn't it? The next sentence?

MS. WAITES: Object to form.

BY MS. ELLIS:

- Q. Go ahead and read the next sentence for the jury.
  - A. Okay.

"Because the additional communication that four associations want relates to their members' CSA roles and responsibility, improved DEA communication with and guidance for registrants may address some of the associations concerns."

So yes to your question. Four is the number.

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Page 112 So is it your understanding that 1 2. Recommendation 2 was based, in part, on feedback from four associations? 3 MS. WAITES: Objection. Calls for 4 speculation. 5 6 MS. MONAGHAN: Yeah. Objection. Foundation. Form. THE WITNESS: Yeah. Like I said, I 8 9 don't know what -- what specifically GAO was 10 thinking here. But it certainly seems reasonable that -- that these concerns raised 11 12 by these associations may have informed their 13 decision making. MS. ELLIS: I have no further 14 15 questions at this time. 16 THE VIDEOGRAPHER: We are going off 17 the record. The time is 11:48. 18 (A short recess was taken.) 19 20 THE VIDEOGRAPHER: We are going back 21 on the record. 2.2 This is the start of Media Unit No. 23 3. 24 The time is 12:05. 2.5 You may proceed, Counsel.

Page 113 MR. MASTERS: We only have a few 1 2. minutes. We'll be as brief as possible. FURTHER EXAMINATION BY COUNSEL FOR CARDINAL 3 HEALTH 4 BY MR. MASTERS: 5 Earlier today you were asked some 6 0. questions about HDA and HDMA? Yes. 8 Α. 9 Are you aware or have knowledge of 10 HDA or HDMA's membership structure? 11 MS. WAITES: Objection. Scope. 12 THE WITNESS: No. 13 BY MR. MASTERS: 14 Are you aware of any of its missions 0. 15 relating to and with respect to its 16 representative members? 17 MS. WAITES: Objection. Scope. 18 THE WITNESS: No. BY MR. MASTERS: 19 20 You don't have any -- any knowledge Q. 21 about the activities that HDMA or HDA engages 2.2 in other than the work that you mentioned on 23 Capitol Hill? 24 MS. WAITES: Objection. Scope. 25 THE WITNESS: Correct.

Page 114 BY MR. MASTERS: 1 2. Ο. Earlier today, when the plaintiffs 3 were questioning you, you were shown a document reflecting questions from the GAO. I -- I -- I 4 can't recall the exhibit. 5 11? 6 Α. 7 11. Yes. That's it. Exhibit 11. Q. 8 And you were directed to some 9 specific questions -- some specific follow-up 10 questions from the GAO. Is that -- do you recall that? 11 12 Α. Yes. 13 Ο. Do these follow-up questions from the GAO go to the substance of the survey 14 15 questions or to the process by which the survey 16 would be administered? 17 MS. WAITES: Objection. Vague. 18 Calls for speculation. Scope. THE WITNESS: I -- I actually don't 19 20 know. 21 BY MR. MASTERS: 2.2 Based on -- based on the plain Ο. 23 language, are -- is the -- is the GAO requesting information about how to maximize 24 25 the responsiveness of the survey?

Page 115 Is that -- would that be a fair way 1 2. to characterize what they're seeking here? 3 MS. WAITES: Objection. Calls for speculation. Scope. Foundation. 4 THE WITNESS: Based on what I'm 5 reading in Question A, the only thing that 6 seems to maybe address your question is how likely would they, who I -- I assuming are the 8 9 distributors, to be willing to or able to 10 complete the survey. 11 BY MR. MASTERS: 12 Is there anything improper about the 13 GAO soliciting input on how to maximize the responsiveness of their survey? 14 15 MS. WAITES: Objection. Calls for 16 speculation. 17 THE WITNESS: No. But I don't --18 I'm not even certain that was -- that's called 19 into question is --20 BY MR. MASTERS: 21 You were also shown a document 2.2 reflecting a communication from DEA to GAO on December 20th, 2016. I believe it was 2.3 Exhibit 10. 2.4 2.5 Α. Yes.

Q. And on the second page of the letter -- I'll just go ahead and show you this -- this has some of my highlighting, but I want to direct you to the -- the paragraph -- the second paragraph of DEA's response states that: "The GAO survey was conducted in 2015 prior to new DEA leadership, including a new acting administrator and new management for the diversion control division. DEA's new management met with industry leaders on February 29th, 2016. Since then DEA has continued to work with the industry and improved communication on these issues."

Did I read that correctly?

A. Yes.

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- Q. In -- in the DEA's response to the GAO and the DEA's status report to the GAO, why did the DEA referenced [sic] new leadership and new management?
- A. So there was a -- a recognition that in -- was it July of 2015 DEA got a new administrator. That was shortly after the former administrator, Michele Leonhart, retired. And one of Acting Administrator Rosenberg's first orders of business was to

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work more in a collaborative fashion with our registrant community.

And so, in -- in -- along that side, he also decided to identify a new person that would run the diversion control program. And that resulted in the former head of diversion retiring.

Q. And this introduction of new management and new leadership in the DEA Office of Diversion Control and at the DEA resulted in improved communications on these issues, fair?

MS. WAITES: Objection.

Mischaracterizes prior testimony.

THE WITNESS: The February 29th,
2016 meeting was a listening session. So this
was our opportunity to basically hear from our
trade associations as to things that they
wanted to communicate with DEA about.

BY MR. MASTERS:

- Q. And the DEA's new management felt that that was a priority?
- A. That was something we absolutely wanted to do, yeah.

And I would say that, under the leadership of Acting Administrator Rosenberg,

Page 118 that was a priority, yes. 1 You also mentioned the distributor 2. 3 initiative as one of the ways in which the DEA communicates in a one-on-one basis with 4 registrants, correct? 5 6 Α. Yes. 7 When was the last time that the DEA Ο. held a distributor initiative briefing with 8 Cardinal Health? 9 10 MR. SMITH: Objection. Scope. 11 THE WITNESS: I don't know. 12 BY MR. MASTERS: 13 Q. When was the last time that the DEA 14 held a distributor initiative briefing with 15 AmerisourceBergen Drug Corporation? 16 MS. WAITES: Objection. Scope. 17 THE WITNESS: Same answer. I don't 18 know. BY MR. MASTERS: 19 20 When was the last time the DEA held Q. 21 a distributor initiative -- initiative briefing 2.2 with McKesson? 2.3 MS. WAITES: Objection. Scope. THE WITNESS: And I'll -- I'll 24 ask -- I don't know the answer. 25

But as a point of clarification, are we talking about an individual McKesson registration location, or are we talking about the corporation at large, which would encompass all their registrations?

BY MR. MASTERS:

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- Q. We're talking about the -- the distributor initiative briefing.
- A. Yeah. Because that's done at a -- at a registrant-specific location. So I don't know the answer to your question.

But just as a point of clarification, if -- if each of these distributors have 20-plus distribution locations, we wouldn't necessarily do the distributor initiative with the corporation at large; it would generally be done with each individual location.

Q. Are you aware that distributor initiative briefings with the corporation at large were, in fact, held in 2005 with Cardinal Health, AmerisourceBergen and McKesson?

MS. WAITES: Objection. Foundation. Scope.

And after this, we're going to stop

questions, both because you're out of time, this is someone else's topic, and we said that we are not going to talk about individual meetings with distributors.

So --

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MR. MASTERS: My --

MS. WAITES: If you have another wrap-up question or two, I'll allow it. But we're not going to continue with this line of questioning.

MR. MASTERS: My understanding from the authorization on this topic that -- that the witness would be off -- prepared to talk about the foundation -- or the basis of the DEA's response to the GAO in its draft -- when -- when it provided the draft report.

And one of the responses that the GA

-- that the DEA gave in its report was, in

emphasizing the communication, they referenced

the distributor initiative briefings that began

in 2005. And I'm simply probing the basis

for -- for that statement.

MS. WAITES: We've been very clear that these depositions are not going to cover specific individual meetings. And if you

wanted to cover that, the appropriate person would have been -- would have been Mr. Provosnik.

So this line of questioning is certainly not appropriate for Mr. Strait. If you have another question regarding the GAO report, I'm fine with that. But you're also out of time.

#### BY MR. MASTERS:

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Q. One final question: Counsel for plaintiffs at -- at Exhibit 9, I believe it was, reviewed a status report from April 27th, 2016, in which the DEA listed a number of communications that it -- or a number of efforts that it took to comply with the GAO's recommendation.

And I just want to confirm for the record that the GAO, in response to this letter, did not close the recommendation, correct?

- A. They did not close the recommendation despite our request that they do so.
- Q. And in -- and in June of 2016, the GAO stated that additional written guidance is

Page 122 still -- has still not occurred and is -- and 1 2. is needed in order to satisfy and close the recommendation, correct? 3 MS. WAITES: Objection. Misstates 4 the document. 5 THE WITNESS: I would just refer you 6 to the -- the plain language in -- in Exhibit 8, which talks about the status as indicated by 8 GAO on their web site. And I can read that if 9 you'd like. 10 11 BY MR. MASTERS: 12 Which -- which is still open, Q. 13 correct? It is still open, yes. 14 Α. 15 MR. MASTERS: No further questions. Thank you. 16 17 THE VIDEOGRAPHER: We are going off 18 the record. The time is 12:15. 19 20 (Discussion held off the record.) 21 THE VIDEOGRAPHER: We are back on 2.2 the record. The time is 12:16. 23 24 We are off the record at 12:16 p.m. And this concludes today's testimony 25

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Page 123
        given by Matthew Strait.
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#### CERTIFICATE OF NOTARY PUBLIC

I, Bonnie L. Russo, the officer before whom the foregoing deposition was taken, do hereby certify that the witness whose testimony appears in the foregoing deposition was duly sworn by me; that the testimony of said witness was taken by me in shorthand and thereafter reduced to computerized transcription under my direction; that said deposition is a true record of the testimony given by said witness; that I am neither counsel for, related to, nor employed by any of the parties to the action in which this deposition was taken; and further, that I am not a relative or employee of any attorney or counsel employed by the parties hereto, nor financially or otherwise interested in the outcome of the action.

pornie L Puro

Notary Public in and for the District of Columbia

My Commission expires: June 30, 2020

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Page 125
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1
                                  1100 Superior Ave
                                     Suite 1820
 2
                               Cleveland, Ohio 44114
 3
                                 Phone: 216-523-1313
      June 5, 2019
5
      To: Natalie A. Waites
 6
      Case Name: In Re: National Prescription Opiate Litigation v.
7
      Veritext Reference Number: 3404564
8
      Witness: Matthew Strait Deposition Date: 5/31/2019
9
10
      Dear Sir/Madam:
11
      Enclosed please find a deposition transcript. Please have the witness
12
      review the transcript and note any changes or corrections on the
13
      included errata sheet, indicating the page, line number, change, and
14
      the reason for the change. Have the witness' signature notarized and
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      If the errata is not returned within thirty days of your receipt of
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		CERTIFICATION	OF WITNESS				
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	Notary Publi	c in and for	the State and	County,			
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Page 127 1 DEPOSITION REVIEW CERTIFICATION OF WITNESS 2 ASSIGNMENT REFERENCE NO: 3404564 CASE NAME: In Re: National Prescription Opiate Litigation v. 3 DATE OF DEPOSITION: 5/31/2019 WITNESS' NAME: Matthew Strait In accordance with the Rules of Civil 5 Procedure, I have read the entire transcript of my testimony or it has been read to me. 6 7 I have listed my changes on the attached Errata Sheet, listing page and line numbers as well as the reason(s) for the change(s). 8 9 I request that these changes be entered as part of the record of my testimony. 10 I have executed the Errata Sheet, as well as this Certificate, and request and authorize 11 that both be appended to the transcript of my testimony and be incorporated therein. 12 13 Matthew Strait Date 14 Sworn to and subscribed before me, a Notary Public in and for the State and County, 15 the referenced witness did personally appear and acknowledge that: 16 They have read the transcript; 17 They have listed all of their corrections in the appended Errata Sheet; 18 They signed the foregoing Sworn Statement; and 19 Their execution of this Statement is of their free act and deed. 20 I have affixed my name and official seal 2.1 this \_\_\_\_\_, 20\_\_\_\_. 22 23 Notary Public 24 Commission Expiration Date 25

			Page 12
	ERRAT	TA SHEET	
V	ERITEXT LEGAI	SOLUTIONS	MIDWEST
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[& - 2nd] Page 1

			(1 ( 00 ( = 0
•	<b>10:14</b> 52:5	19 53:9	64:6,23 65:2
<b>X</b> Zio 5:10 4:2.0	<b>10:36</b> 70:7	19103 5:4	66:19,24 68:16,20
7:3 9 6:4 10 15 71	<b>10:57</b> 70:11	2	<b>2019</b> 1:20 10:5
10:22 11:9,11,16	11 6:10 9:3 99:20	<b>2</b> 8:10 15:10,11	67:2 68:24 69:4
11:20,21 12:15,17	99:24 114:6,7,7	30:2,8 52:4 57:9	69:16 125:4
12.18 13.2 5 5 11	<b>1100</b> 4:10 125:1	57:17 58:8,12	<b>202-434-5000</b> 5:11
0	113 8:4	63:13 77:22 81:24	<b>202-598-6204</b> 3:12
0.05.10.10	<b>11937</b> 124:19	82:1,3,4 86:7	<b>202-616-2964</b> 3:7
0000=1	<b>11:43</b> 109:1	108:7,25 110:13	<b>202-662-6000</b> 6:6
0000000000	<b>11:44</b> 109:7	112:2	<b>202-778-1800</b> 5:17
0.4-	<b>11:48</b> 112:18	<b>2-20-14</b> 9:3	<b>2020</b> 124:23
	<b>12</b> 9:5 104:16,20	<b>2-26-18</b> 8:18	<b>20th</b> 61:18 62:13
<b>00026799</b> 80:19	107:14	<b>20</b> 14:21 17:12	62:15 63:20 85:12
0.00	<b>12-20-16</b> 8:23	119:14 126:16	86:5 102:14,17
	<b>12:05</b> 112:24	127:22 128:22	115:23
	<b>12:15</b> 122:19	<b>200</b> 26:7,19 39:6	<b>21</b> 15:23 16:20
	<b>12:16</b> 122:23,24	90:6	38:22 89:10,22,25
8:24	123:6	<b>20001</b> 6:5	<b>213-430-7508</b> 4:6
	<b>12th</b> 2:6 5:10	<b>20001</b> 0.3 <b>20002</b> 3:7	<b>215-963-4824</b> 5:5
00026833-834	10:22	<b>20002</b> 5:7 <b>20005</b> 5:10	<b>2150</b> 3:16
	<b>13</b> 8:3 43:12 111:4	<b>2003</b> 5:17	216-523-1313
	<b>14</b> 8:9 111:1,4	<b>2005</b> 3.17 <b>2005</b> 119:21	125:3
	<b>15</b> 8:10 43:12	120:21	<b>216-592-5000</b> 4:11
	<b>15-471</b> 8:20	<b>2006</b> 84:19	<b>21st</b> 81:13
<b>02423059-064</b> 9:6	<b>15219</b> 6:22	<b>2011</b> 29:12 43:15	<b>22152</b> 3:11
1	<b>15222</b> 5:23	<b>2011</b> 29:12 45:13 <b>2013</b> 82:23 95:14	<b>225</b> 5:23
1 8:9 10:14 14:23	<b>15471</b> 23:16	95:22 96:3 100:8	<b>23</b> 8:11
	<b>16</b> 27:7 43:12	<b>2014</b> 90:16 102:14	<b>24</b> 111:2
73:6,21 91:9	97:15 111:2	102:17 104:23	<b>25</b> 32:13 33:17
<b>1,700</b> 40:25	<b>16-737t</b> 52:13	<b>2015</b> 23:22 65:23	<b>25th</b> 73:14
1.7 26:13	<b>17</b> 1:5,9 10:20	73:15 81:13 82:23	<b>26</b> 27:3 31:13
<b>1.8</b> 76:20	50:7 111:5	116:6,21	97:14 111:2
	<b>1701</b> 5:4	<b>2016</b> 54:4 55:6	<b>27</b> 34:5
	<b>175</b> 3:6		<b>27th</b> 81:4 86:1
87:18 88:13 111:5	<b>1755</b> 4:15	81:4 82:24 85:13	121:12
	<b>18</b> 1:11,13	86:1,5 88:16 89:1 115:23 116:11	<b>28</b> 92:10
113.21	<b>18,000</b> 40:24		<b>2804</b> 1:4,5 10:20
10-13-14 J.J	<b>1800</b> 5:16	117:15 121:13,24	<b>29th</b> 116:11
	<b>1820</b> 125:2	<b>2017</b> 17:17 49:25	117:14
1000 3.10	<b>18th</b> 4:5	57:6,24 63:20,21	<b>2nd</b> 63:21
107 7.3		<b>2018</b> 61:18 62:14	
		62:15,22,22 63:9	

[3 - additional] Page 2

	46 46 5	<b>70</b> 00 7 (	1 07 04 40 5
3	46 46:5	<b>78</b> 90:5,6	abuse 27:24 42:5
<b>3</b> 8:11 23:8,13	<b>46204</b> 6:11	<b>79</b> 48:10	acceptable 41:14
71:2 72:8 73:6	47 8:13	8	access 34:18,25
74:18 77:23 89:11	<b>48202</b> 3:17	<b>8</b> 8:20 15:22 65:8	35:22 66:1 94:4
92:14 97:6 109:6	5	65:12 107:12	103:24
112:23	<b>5</b> 8:14 40:1 52:7	109:10 122:8	accessible 46:12
<b>30</b> 19:19 124:23	52:11 125:4	<b>80</b> 8:21	accountability
<b>300</b> 26:8,11	<b>5-24-19</b> 8:10	81 39:25	18:12,17,22 19:15
<b>301</b> 6:22	<b>5/31/2019</b> 125:8	<b>85</b> 8:23	71:8,13,21 100:4
<b>3011</b> 3:16	126:3 127:3	<b>850</b> 6:5	accurate 42:11
30th 62:22 63:9	<b>52</b> 8:14	<b>8701</b> 3:11	acknowledge
<b>31</b> 1:20	<b>53202</b> 6:16		126:11 127:16
<b>312-269-4066</b> 4:20		9	acknowledges
<b>312-209-4000</b> 4:20 <b>312-646-5817</b> 3:22	<b>55</b> 110:6,17 <b>56</b> 8:16	9 8:21 26:20 80:6	44:23
<b>312-040-581</b> 7 3:22 <b>313-800-4170</b> 3:17		80:7,15 86:2,21	act 48:5 72:5,11
	6	87:2,3,16 88:12	126:14 127:20
<b>317-261-7863</b> 6:11	<b>6</b> 8:16 19:19 27:18	121:11	acting 116:8,24
31st 10:5 69:5,16	56:8,12 63:12	900 26:20	117:25
<b>3400</b> 3:21	92:14	90071 4:6	action 33:14
<b>3404564</b> 1:25	<b>6-9-17</b> 8:16	<b>92</b> 109:24	124:12,17
125:7 126:2 127:2	<b>60601</b> 3:22 4:19	<b>94303</b> 4:15	actions 57:3 75:8
128:2	<b>61</b> 8:18	<b>945</b> 26:20	78:1 80:1 82:14
<b>35</b> 3:21	<b>65</b> 8:20	<b>950</b> 4:9	82:18 87:6 88:2
<b>35th</b> 6:21	<b>650-739-3939</b> 4:16	<b>954</b> 90:14	activities 75:2
<b>36</b> 110:6,17	<b>66</b> 89:13,14	99 9:3	113:21
4	<b>67</b> 74:17,20	<b>9:21</b> 24:13	
4 8:13 47:2,6 89:4	,	<b>9:24</b> 24:17	added 50:1,6 106:14
<b>4-27-16</b> 8:21	7	<b>9:59</b> 51:24	
<b>40</b> 38:2	7 8:18 61:10,14	7.37 31.24	addition 27:10
<b>400</b> 4:5 26:8,14	<b>70</b> 8:5 60:25	a	88:11
<b>412-288-3131</b> 5:24	<b>71,000</b> 26:11 40:23	<b>a.m.</b> 1:21 10:5	additional 30:11
	47:20 76:3,9	aaron 1:7	30:16,17,24 31:20
412-338-5224 6:23	<b>715</b> 76:7,8,9 90:10	ability 67:11	32:19 33:3,10
<b>414-297-5913</b> 6:16	<b>725</b> 2:6 5:10 10:22	able 40:18 45:25	37:19 42:7,25
44 30:5 44:14	<b>73</b> 61:1	101:9 115:9	43:24 44:10 45:2
44113 4:10	<b>750</b> 26:21 38:24	absence 33:20	46:10,15,15 48:12
44114 125:2	76:6,8,9 90:10	34:11 35:18 36:13	48:13 49:17,17
<b>45</b> 38:3 44:23 60:3	<b>77</b> 4:19 39:7,11	36:23	50:24 51:11 54:18
<b>45005</b> 1:9	73:5,13 90:1,6	absent 64:2,10	55:2 58:22 59:14
<b>45090</b> 1:13	91:12 92:11	absolutely 21:6,13	59:24 60:10 64:3
<b>45132</b> 1:11	777 6:16	29:3 60:12,15	64:24 69:18 80:3
		68:13 84:9 117:22	86:8 88:15 110:4
		10.13	

[additional - audio] Page 3

111 10 121 25	101 16 111 2 5	04 11 14 22 05 5	50 1
111:18 121:25	101:16 111:2,5	94:11,14,23 95:5	asking 58:1
additionally 34:7	agency 17:23	96:1 104:12	aspects 83:7
34:11	18:13 20:19 22:9	106:25 110:22	assertion 37:1
address 22:4	32:25 44:15 45:25	118:17,25 119:11	assessment 40:19
24:10 57:3 111:22	56:20 66:20 74:25	answered 51:15	assignment 126:2
115:7 125:15	75:5 86:15 93:14	answers 89:23	127:2 128:2
addressed 44:5	99:10	anthony 5:15	assist 48:3
addressing 21:12	agency's 57:18	11:12	assistance 71:17
27:24	<b>agenda</b> 50:2,7	anticipated 66:24	assistant 16:25
adequacy 25:10	<b>ago</b> 53:12 54:2	anticipates 64:3	17:4 37:13
29:17	57:8,23 90:9	anybody 94:18	assisting 19:22
adequate 24:24	agree 10:13 25:6	apologize 80:13	association 83:4
72:18,23	34:19,23 37:1	<b>appear</b> 126:11	98:13
administered	49:5 71:22 72:21	127:15	associations 27:4
41:10 97:9 114:16	74:6,24 78:13	appearances 3:1	27:12 30:9 45:1
administering	agreement 23:5	4:1 5:1 6:1 11:6	82:5 83:7 87:7,9
73:24 104:2	ahead 11:23 32:11	appears 61:16	88:3,6,22 96:21
administration	105:22 106:3	66:3,11 80:24	97:14,19,23 98:6
3:10 12:4 14:20	111:15 116:2	88:12 124:5	108:10 111:3,5,8
16:6,10,15,23	aid 5:2 13:8	appended 127:11	111:11,19,23
17:10 18:23 19:2	<b>al</b> 1:8,10,12,13	127:18	112:3,12 117:17
21:3 29:6 48:2	alliance 96:17	appropriate 41:4	assuming 105:15
52:25 56:23	<b>allow</b> 120:8	121:1,5	115:8
administrative	alongside 99:7	approval 61:7	attached 86:4
75:7	<b>aloud</b> 88:18	63:18	127:7
administrator	109:20 110:25	approximately	attachment 8:18
16:25 17:5 37:14	<b>alto</b> 4:15	76:3 91:22	8:22,24 85:16
116:8,22,23,24	american 71:14	april 54:4 55:5	89:4 107:17
117:25	amerisourceberg	81:4 86:1 121:12	attempt 86:15
advance 80:16	5:20 12:25 101:21	arbitrary 34:23	attendee 103:18
advise 17:5	102:1 118:15	35:3 36:6 39:15	attending 11:5
advisor 16:24 17:3	119:22	40:7 41:21 45:9	106:1
17:9	amount 33:21	argue 41:20	attention 15:22
<b>affairs</b> 17:21 24:4	34:14 36:15 41:24	arm 71:10 72:1	27:17 75:18 91:8
98:15	98:18,23	aruiz 5:18	92:13 107:11
<b>affect</b> 76:12	analyses 71:16	aside 51:5	109:15
affiliations 11:6	analysis 60:23	asked 25:9,16	attorney 124:15
<b>affixed</b> 126:15	anda 6:13 13:12	29:14 39:1,2,11	attorney's 7:3
127:21	angeles 4:6	51:14 62:12 75:15	12:6
<b>agencies</b> 18:9 27:8	answer 14:14 34:3	82:8 102:15 113:6	<b>audio</b> 10:11,11
27:13 67:21 97:15	59:5 84:5 89:8		12:23
		10.1.	

[audit - certainly] Page 4

audit 20:23 21:18	122:21 125:15	121:11	c
21:21,24 55:21	barnes 6:10,20	beneficial 32:22	
56:18 61:17 71:9	12:15,17,17	33:6,11	c 3:9 4:8 8:1 10:1
72:1 81:2 85:19	barring 51:5	<b>benefit</b> 47:19	ca 125:25
103:7	base 87:21	87:25 106:14	cah 9:6
audits 77:5	based 27:10 41:6,7	best 76:22	california 4:6,15
august 14:21	41:10 55:7 56:4	better 20:1 43:22	call 21:25 24:24
64:23 66:24 68:16	58:8 60:19,22	<b>beyond</b> 51:2	96:4 100:9
96:3 100:8	86:16,18 87:6	bhimmel 5:24	called 26:6 50:25
author 83:24	88:2 89:18 97:10	bit 59:2 95:10	56:22 84:17 97:25
authorization	112:2 114:22,22	bmasters 5:12	115:18
15:15 120:12	115:5	boards 83:5	calls 50:12 59:18
authorize 127:11	basically 40:21	<b>bob</b> 106:18	78:25 79:8,15
authorized 15:17	117:16	bockius 5:3	107:7 112:4
16:18	basis 51:8 103:25	<b>bonnie</b> 1:24 11:2	114:18 115:3,15
availability 42:3	118:4 120:14,21	124:2	capacity 15:16
74:1,3	bates 65:13 80:17	<b>books</b> 60:3	17:18 24:3
available 107:25	99:24	<b>bottom</b> 24:23 25:2	capital 98:16 99:5
109:11	<b>began</b> 84:18	66:3 77:25 80:18	capitol 113:23
ave 125:1	120:20	boulevard 3:16	<b>cardinal</b> 5:7 11:9
avenue 4:9 5:23	beginning 27:19	brad 5:9 11:8	11:11 13:23
average 40:18	31:17 34:7 46:7	branch 50:21	101:21,23 113:3
aware 18:20 23:20	52:3 53:19 88:13	63:16	118:9 119:21
23:25 24:4,6 53:2	behalf 2:10 3:3,13	break 51:19	careful 50:17
79:3,3,11 81:8	3:19 4:2,12 5:2,7	<b>brian</b> 5:21 12:24	carl 105:6,8
92:24 93:1 94:25	5:13,20 6:2,8,13	<b>brief</b> 113:2	case 1:5,9,11,13
95:12,20 96:3,9,19	6:19 11:13,16,20	<b>briefing</b> 118:8,14	10:19 36:21 37:22
97:19 102:3,15,20	11:22 12:7,9,16,18	118:21 119:8	56:16 60:7 67:23
104:21 113:9,14	12:21 13:2,5,8	briefings 119:20	70:22 108:3 125:6
119:19	16:9 37:7 52:23	120:20	126:3 127:3
b	53:10,24	bringing 41:8	cause 64:15
	beisell 4:17 12:20	brought 99:9	cc 81:17
<b>b</b> 19:19 101:13	12:20	btlaw.com 6:12	cell 10:9
bacchus 7:2 12:5,5	believe 20:6 29:9	<b>budget</b> 63:22	cellular 10:8
back 17:16 23:22	31:13 43:20 46:9	67:18	centre 6:21
24:15 29:25 30:21	52:16 54:20 80:15	<b>burling</b> 6:4 11:16	certain 20:21
33:16 36:2 43:15	84:18 89:15 90:14	burned 106:7	29:13 34:14 36:15
47:9,10 52:1 56:1	90:14,17 92:15,23	business 20:16	84:2 96:21 115:18
63:11 70:9 71:1	93:13,23 94:16	36:7 116:25	certainly 43:9
75:18 90:16 91:8	96:16 97:21 98:5	businesses 87:9	84:14 98:5 112:10
94:22 97:5 108:14	110:9 115:23	88:5	121:5
109:3 112:20			

## [certainty - congress]

certainty 84:2	clear 33:20 34:12	commenting 53:10	complete 101:9
certificate 124:1	35:18 36:13,23,23	53:20,21,25	115:10
127:11	51:10 55:16 56:7	comments 23:6	completed 64:5
certification 126:1	59:20 120:23	31:22 44:9,15	125:15
127:1	clearly 59:19	66:6,18	completely 41:5
certify 124:4	cleveland 1:10	commerce 100:18	compliance 56:17
cetera 106:12	4:10 125:2	commission	72:10
chain 9:3,5 35:11	clients 99:5	124:23 126:19	comply 15:24
76:25 97:12	close 22:1,2 47:7	127:25 128:25	48:14 53:11 54:1
101:10 110:3	49:19 55:12,17	commitment	83:13 121:15
challenges 83:9	56:3 57:12 58:7	71:19	computerized
change 125:13,14	121:19,21 122:2	committee 8:14	124:8
127:8 128:3	closed 51:9 57:7	52:16,16 100:18	concern 98:22
changes 23:3 91:6	57:10,25	<b>common</b> 106:10	106:6
125:12 126:7	closeout 56:20	communicate	concerned 33:19
127:7,9	closing 55:6,22	117:18	concerning 29:22
characterization	closure 86:18,22	communicated	concerns 44:24
32:6	87:1,5,19 88:1	37:22 109:25	59:4 98:18 111:23
characterize 115:2	coalition 87:11	communicates	112:11
charge 84:25	collaborate 85:1	76:13 99:13 118:4	concerted 107:3
charged 19:22	collaborating 87:8	communication	conclude 33:3
74:4	88:5	24:25 25:21 31:11	concluded 123:6
<b>chart</b> 92:6	collaboration	31:23 32:21 78:2	concludes 122:25
chemical 90:22	67:13,14	98:19,23 99:9	conclusion 79:1,8
chemicals 90:21	collaborative	110:4,7,11 111:9	79:15
<b>chicago</b> 3:22 4:19	117:1	111:19,21 115:22	conduct 25:20
<b>chief</b> 3:10 17:20	colleagues 106:11	116:13 120:19	77:5
56:17	columbia 124:21	communications	conducted 26:1
circumstances	<b>column</b> 66:4,5	15:23 25:11,17	116:6
41:4	<b>come</b> 19:25 20:17	27:14 29:1 30:16	conference 82:22
<b>city</b> 1:10	47:9	56:1 117:11	83:19 84:23 89:1
citycenter 6:4	comfortable 69:12	121:14	96:4 100:9 108:17
civil 3:5 7:4 126:5	<b>coming</b> 36:19,20	community 26:12	conferences 43:11
127:5	47:10 84:24	38:5 43:11 77:9	54:9 55:7 56:4
clarification 38:21	comment 23:5	84:17 117:2	83:2 87:10 88:7
119:1,13	45:15 60:6,10,13	companies 102:2	88:16 89:2
clarified 89:16	60:15 63:3 64:4	company 12:19	<b>confirm</b> 121:17
clarity 100:20	73:10	comparable 33:1	congress 17:23
class 79:21,23	commented 38:18	49:8 58:24 59:9	18:10,16 19:6,22
classes 79:18	110:6 111:6	69:23 91:4	20:1,10,25 25:10
			52:23 71:10,10,18

[congress - dan] Page 6

72 2 01 17 16	77.10.116.0.117.5	51 10 50 05 50 1	1065
72:2 81:15,16	77:12 116:9 117:5	51:13 52:25 53:1	126:7
98:17	117:10	53:13 54:2,3,12	cov.com 6:6
congress's 18:2	controlled 26:21	56:24 57:4,5,13	cover 66:11
congressional 8:11	33:22 34:14 36:15	58:5,20 59:1,10,16	120:24 121:1
17:21 18:5 19:9	38:25 48:4 65:25	60:1,11,18 61:8,21	covington 6:4
24:3 52:14 81:12	67:23 72:5,10	61:23 62:5,6,10	11:16
98:15	74:1,5 75:4 77:1	63:10,25 64:19,22	crafting 110:21
connecting 36:22	83:11 90:18,25	65:2,14,15 66:1,2	create 34:25 35:4
connects 36:9	98:11	66:7,16 67:4	41:23 42:1 45:25
connolly 2:5 5:9	controlling 20:24	68:12,21,22 69:2	49:13 105:14
10:22 11:9,11	conversations	78:15,19 81:20	created 32:23
consensus 83:8	10:8 102:25 103:7	85:14,24 87:17	46:19,23
consequence 42:4	coordinating 75:1	88:17 91:13 93:1	csa 45:24 48:14
conservative	106:10	103:2 104:6,9	54:24 73:25 78:3
33:21	coordination	108:12 113:25	78:15,22 79:5
consideration	67:17	118:5 121:20	82:16 83:15
21:22 23:3 26:10	<b>copy</b> 80:9 81:17	122:3,13	103:24 104:23
considered 60:5	<b>core</b> 71:20	corrections 125:12	110:5 111:20
considers 60:6	<b>corner</b> 41:13	127:17	culminate 24:6
consistent 28:8	77:25	correctly 28:6	<b>current</b> 16:22 17:8
consistently 21:24	corporate 35:11	31:25 46:3 48:7	58:14 62:4,18
constituted 84:3	36:21 97:12	54:11 58:19 67:3	66:21
constitutional	101:13,17 110:3	116:14	currently 49:19
71:11	corporation 5:20	correspondence	75:24
contained 15:25	6:2 12:25 118:15	55:5,21,23 56:16	customer 29:12
containing 75:4	119:4,16,20	56:20	40:12,13 45:22
contains 62:1	<b>correct</b> 16:6,7,11	<b>counsel</b> 3:10 10:16	91:14
content 95:2	16:15 18:13 22:10	11:4 13:22,23	customers 34:15
<b>contents</b> 47:22,24	22:11,17 23:18,19	14:13 24:18 52:6	36:17 39:19 41:1
continue 10:12	25:13,19 27:5,6,9	70:12,17 109:8	41:19
30:7 46:9 54:19	27:15,16 28:14,15	112:25 113:3	<b>cut</b> 80:17
87:8 88:4 120:9	29:2,6,19 30:18	121:10 124:11,15	cuyahoga 1:8
continued 4:1 5:1	31:12,15 32:1	counterparts	evs 5:13,13 11:13
6:1 9:1 51:3 88:14	33:11 35:7,23	85:20	11:13
88:21 116:12	36:17,18 37:4,5,7	<b>county</b> 1:8,12	d
continues 43:15	37:10,20 38:1,10	126:10 127:15	<b>d</b> 10:1
<b>control</b> 17:1,6,17	38:14 39:20 42:16	couple 101:5	<b>d.c.</b> 1:19 2:7 5:10
24:24 27:22 28:13	42:17,19 43:2,4,24	course 21:14	5:17 6:5 10:23
28:20,22,23 37:14	44:6,21 45:15,20	28:10 48:15 77:12	da 68:17
37:15,17 48:3	46:4,16,17 47:16	<b>court</b> 1:1 10:18	dan 1:6
61:8 73:23 74:8	48:8,10,11,16,25	11:1 13:13 14:9	uan 1.0

[daniel - direct] Page 7

<b>daniel</b> 7:6 10:24	54:15,17,25 55:17	67:10 73:23 74:7	15:5,11 16:13
data 34:12 36:14	56:16 57:2,11	74:24 81:16 82:3	23:8 47:2 52:7
36:23	58:3,4,13,23 59:6	82:22 83:2,4 87:6	56:8 61:10 65:8
database 103:25	59:7,15 60:8 62:3	88:2 91:13,18,25	80:7,16 85:6
104:5	62:7 63:7 64:3,23	116:5,9,16,17	99:20 104:16
date 86:3 102:13	65:14,23,24 66:19	117:20 120:15	124:3,5,9,13 125:8
125:8 126:3,9,19	66:23,23 68:18	deadlines 20:25	124.3,3,9,13 123.8
127:3,13,25	69:6,17,19,22	dear 125:10	127:1,3
128:20,25	72:15 73:1,11,18	december 85:12	depositions 120:24
dated 8:10,16,18	74:12 75:7 76:13	86:5 115:23	depth 108:8
8:21,23 9:3,5	76:21 78:1 79:13	dechert 3:20 11:18	deputy 37:13
61:18 73:14 81:3	79:25 80:1,3,3,19	dechert.com 3:23	describe 82:13
81:12 85:12	82:1,9,14,19 83:12	decide 106:17	described 68:17
dates 103:4	83:24 84:3,14,21	decided 104:1	88:11
david 7:4 12:1	84:23 85:1,2,4,5	117:4	describing 66:5,6
	85:25 86:9,10,22	decision 36:7	
<b>day</b> 4:14,18 12:21 13:10 19:7,7	86:24,25 87:1,4,8	112:13	description 88:15 design 45:18
43:15 126:16	87:18 88:1,4,13,21	decisions 71:19	designation 19:19
127:22 128:22		declined 58:7	
	88:25 89:2,6 91:7		<b>despite</b> 121:22 <b>detail</b> 17:13 18:1
days 125:18 dc 3:7	92:25 93:4,8,18	deed 126:14 127:20	details 50:18
	94:2,6,13,19 97:11		detroit 3:17
de 82:9	97:14 98:19,24 99:7,13 100:5,20	deemed 125:19 defendant 10:16	develop 30:10,23
dea 8:17,19,20,22		define 42:22	45:2 54:18 55:1
8:24 12:7,9,11 18:4,7,11,16 21:5	101:7,15 102:4,15 102:24 103:10,17	defines 42:12	58:22,23 59:8,14
21:7,18 22:17,21	<u> </u>	delay 63:18	
	103:24 106:13,15 106:19 108:8	•	<b>developed</b> 32:25 49:7
23:7 25:6,17		delays 64:16	
27:13,21,23,25	109:22,25 110:5,8	<b>deliberative</b> 20:19	developing 45:23
28:9,13 29:1	110:8 111:4,7,9,21	49:24 50:17 69:11	deviating 42:14
31:12,21,24 32:2 32:10,23 33:14	115:22 116:7,11	delivered 68:25	diana 52:14,19
	116:18,21 117:9 117:10,18 118:3,7	demand 74:4 deo 72:25	<b>differ</b> 39:19 40:11 <b>difference</b> 75:16
34:12,19 36:13	· · · · · · · · · · · · · · · · · · ·		
37:3,7,20 38:5	118:13,20 120:18	<b>department</b> 3:3,5	90:17 <b>different</b> 27:8 41:5
39:8,14 40:8,15,17	121:13	3:9 7:3,4 12:2	
40:22,24 41:15,19	dea's 17:21 23:2	44:20 50:1 66:25	41:11,14 57:22
41:22 42:2,6,25	25:11 28:2,8	67:6,15,22 68:2,7	76:14 77:14 78:21
43:9,18 44:5,10	29:17,22 37:18,23	125:22	79:5,12,18,22
45:16,23 46:10,19	38:8 40:19 44:2,8	deposed 14:3	81:19 84:22 90:11
46:23 47:14 48:20	44:24 45:14,15,22	<b>deposition</b> 1:18	diligence 100:21
49:7,22 50:1,23	47:12 53:10,25	2:1 8:9 10:11,15	direct 15:21 27:17
51:11 53:4 54:5	58:11 62:1 63:12	10:21 14:24 15:5	73:5 74:17 75:17

[direct - ellis] Page 8

01 22 04 20 06 6	04 10 22 00 2	20 12 20 22 22	16 5 0 14 22 17 10
81:23 84:20 86:6	84:18,22 89:3	28:13,20,22,22	16:5,9,14,23 17:10
89:10 92:13	96:16 100:4 101:7	32:9 37:14,15,16	18:22 19:2 21:3
101:14 107:11	118:2,8,14,21	37:17 42:4 48:2	27:24 29:5 48:1
109:14 116:4	119:8,16,19	61:7 73:1,23 74:3	52:24 56:23 75:1
directed 114:8	120:20	74:7 77:12 100:16	76:24 101:10,22
directing 91:8	distributors 25:12	116:9 117:5,6,10	101:24 118:15
direction 124:9	25:18 26:8,17,18	division 1:2 3:5	<b>drugs</b> 35:21 75:4
directive 78:10	26:23 27:1 29:18	10:19 17:1 28:23	due 100:21
directives 63:17	29:23 30:9,10,11	61:8 116:9	<b>duly</b> 13:17 124:5
63:19 64:11	30:17,24 31:5,9,22	doctors 46:20	e
<b>directly</b> 17:4 51:4	32:4,10,19 33:2,4	<b>document</b> 1:6 15:2	e 6:3 8:1,18,21,23
81:22 84:6	33:20 34:13,22	15:8,14,18 23:14	9:3,5 10:1,1 80:15
director 52:20	35:19 36:5,8,14	29:12 30:20,20	85:15,17 86:4
disagreement 23:6	37:22 38:17,25	33:1 35:25 36:9	100:2 101:19
disclose 45:19	39:6,8,16,19 40:8	47:11,19,25 48:19	100.2 101.19
disclosing 50:14	40:16 41:1 43:7	49:8,15 50:18	107:17
discussed 32:6	44:11 45:1,2,3,9	52:12 54:20 56:13	earlier 20:9 75:16
33:8 51:3 55:20	45:18 46:11,21	58:24 59:7,9	79:24 84:1,5
79:24 85:23 89:11	47:16,18 49:23	61:15 65:12,13,16	89:11,15 92:15
107:19 108:7	50:24 51:12 54:6	69:23 80:21,23	102:24 107:19
discussing 53:12	54:10,19,22 55:3	81:24 83:9,22	
54:2 109:10,13	57:10 58:16 59:24	85:9,17 87:16	113:6 114:2
discussion 57:18	60:9 66:10 69:18	97:4,7 114:3	early 95:13,22
88:24 108:19	75:17 76:5,9,11	115:21 122:5	east 6:16
122:20	77:2 78:22 79:4	documents 27:21	eastern 1:2 10:19
discussions 104:9	79:13,21 82:5,6,10	29:5,8,11,13 83:21	editing 61:6
105:12	82:15 83:14 84:7	92:17	educate 54:6
dispensed 41:9	84:21,24 86:11	doing 18:3 20:15	82:14
dispensing 83:11	87:7,8,12 88:3,4,8	55:14 86:9,15	effort 50:6 107:3
distinction 90:15	88:14,22,25 89:1,7	doj 11:25 12:7,9	efforts 15:24 51:3
distribute 54:18	89:8 90:2,4,10,18	double 65:12	53:11,25 54:5
55:2	90:25 91:7,17	downside 106:13	57:19 68:6 77:16
distributed 41:22	97:11 98:11	draft 37:3 44:9	83:12 88:11
distribution 90:21	109:24 110:2,6	61:5 66:22,25	100:16 121:15
119:14	115:9 119:14	68:2 120:15,16	ellis 3:14 4:9 8:5
distributor 34:25	120:4	drafting 57:19	11:21,21 13:2
35:14 40:12,12	district 1:1,1	67:9 68:6	70:18,21 73:4
41:16,17 43:10,11	10:18,19 12:7	drastic 91:5	74:11,16 75:14
43:14 46:12 49:9	124:21	drive 3:11,21	76:18 77:20,21
54:8 60:8 82:22	diversion 16:25	drug 3:10 5:20	79:2,10,24 80:11
83:18 84:5,12,16	17:6,17 27:22,25	12:3,25 14:20	80:14 85:3,8 92:2
03.10 0 1.3,12,10	11.091121.22,23	12.0,20 11.20	92:12 93:17 94:1

[ellis - finkelstein] Page 9

94:12 95:6,11,17	engages 113:21	<b>exhibit</b> 8:9,10,11	fact 31:8 38:13
96:2,10,18 97:3	ensued 19:10	8:13,14,16,18,20	40:11 68:23 79:18
98:7,20 99:11,22	<b>ensure</b> 21:19 66:1	8:21,23 9:3,5	85:24 119:21
102:8,21 103:16	ensuring 74:1	14:23,24 15:10,11	factors 41:11
104:4,13,18 105:2	entered 127:9	23:8,13 47:2,6	facts 73:19
107:1,10 108:16	<b>entire</b> 104:5 126:5	52:7,11 56:8,12	fair 32:5 39:13
108:21 109:9	127:5	61:10,14 63:12	115:1 117:11
110:18,23 111:14	entitled 83:9	65:8,12 71:2 72:8	<b>fall</b> 49:25 50:7
112:14	environment	73:6 74:18 77:23	familiar 79:17
<b>elmo</b> 24:10	43:21	80:6,7,15 85:4,6	93:6
else's 120:2	errata 125:13,18	86:2,21 87:2,3,16	far 93:3
email 125:17	127:7,10,18 128:1	87:18 88:12,13	<b>fashion</b> 21:1 117:1
embarcadero 4:15	esq 3:4,9,14,15,20	89:11 92:14 97:6	february 61:18
emphasize 73:18	4:4,8,13,17 5:8,9	99:20,24 104:16	62:13,15 63:21
emphasizing	5:15,21 6:3,9,14	104:20 107:12,13	66:19 102:14,16
120:19	6:20 7:2,4	107:19 109:10	116:11 117:14
employed 124:12	essentially 71:25	114:5,7 115:24	<b>federal</b> 18:3 24:23
124:15	established 40:22	121:11 122:7	25:5 48:4 50:5
employee 124:14	et 1:8,10,12,13	exhibits 8:8 9:1	60:2 62:17,20,25
enclosed 125:11	106:12	existing 59:16	63:10 64:4 68:11
encompass 119:4	evaluates 71:15	exists 58:25 69:24	68:19 69:20 71:13
encompassed	evaluation 44:15	71:10	71:15 101:15
30:15	71:9 72:1	expand 38:6	feedback 91:18
<b>ended</b> 31:9,19	event 105:24	experience 19:24	93:3,9 96:21
39:2,3 89:21	examination 8:2	20:4 22:15	112:3
<b>energy</b> 100:18	13:23 70:17 113:3	expiration 126:19	feel 14:12 38:12
enforcement 3:10	examines 71:14	127:25 128:25	59:4 69:12 86:24
12:4 14:20 16:5	example 32:23	expires 124:23	feels 41:15
16:10,15,23 17:10	56:15 101:10	explain 19:14	<b>felt</b> 57:11 117:20
18:22 19:2 21:3	109:24 110:6	40:14	<b>field</b> 109:25
29:6 48:2 52:25	excellent 89:2	explained 37:20	<b>fifth</b> 5:23
56:23 75:2,5,8	exchange 20:22	explains 48:22	<b>filed</b> 10:17
enforcing 72:5	excluding 90:22	extensive 60:4	<b>final</b> 23:4 64:4
73:24	excuse 34:24	67:13	68:11,15 121:10
<b>engage</b> 77:13 89:3	54:16 64:14	extensively 98:17	financially 124:16
engaged 27:24	executed 127:10	<b>extent</b> 50:12 59:17	<b>find</b> 31:20 94:22
engagement 28:9	execution 126:14	83:18	125:11
77:2 84:21	127:19	f	<b>fine</b> 49:5 50:15
engagements	executive 50:20	face 43:21,21	121:7
43:13	63:14,16	facilitated 67:17	finkelstein 7:4
			12:1,1
		val Calutions	

[firm - go] Page 10

<b>firm</b> 10:25 11:2	94:9 95:3,15,16,25	<b>fulsome</b> 60:23	85:19,21 93:4
99:4	96:8,14,23 98:2,9	<b>function</b> 21:19	94:20 95:12,20
first 13:17 14:5	99:1,15 102:19	<b>funding</b> 71:19	96:4,20 97:13
23:20 24:21,22	103:21 104:10,24	funds 71:15	100:9,25 103:1,11
25:3 32:16 33:17	106:23 107:5	furnished 100:17	103:20 104:1,9,21
40:3 59:11 60:17	111:13 112:7	further 54:22	105:16 106:7
66:11 67:2,14	<b>formal</b> 18:6 60:12	70:14 83:14	107:24 108:1
68:1,24 71:4 73:8	<b>former</b> 116:23	100:20 112:14	109:11,12 110:20
73:10,11,12 77:24	117:6	113:3 122:15	111:1 112:9 114:4
81:7,11 82:21	<b>forth</b> 56:2	124:13	114:10,14,23
85:24 91:11 94:19	<b>forward</b> 125:15	furthermore	115:13,22 116:6
100:6 105:3,12	<b>found</b> 33:9 38:11	31:18,18	116:17,17 120:15
108:14 109:15	44:10 46:18 91:24	g	121:6,18,25 122:9
116:25	92:6 109:25	g 10:1 34:23 73:17	gao's 22:16 23:15
<b>fiscal</b> 62:21 63:8	foundation 33:25	103:17	28:9 30:15 36:12
64:6 65:2 67:2	65:4 95:23 96:6	ga 72:4 94:25	57:4 58:3,21
68:20,24	96:22,24 98:3	103:1 120:17	59:14 65:17 66:14
<b>five</b> 17:15	99:16,18 103:14	gaa 86:9	66:18 71:5,19
<b>flag</b> 83:10	103:22 104:25	gao 8:20 16:1 19:3	80:2 83:13 86:10
flip 35:2 41:25	106:23 107:6	19:4,7,21,24 20:4	89:17 107:4
71:1	112:7 115:4	20:10 21:2,9,12,17	110:13 121:15
<b>floor</b> 4:5 6:21	119:23 120:14	21:18,20 22:5,8,19	<b>ge</b> 100:24
<b>focused</b> 78:14,18	four 27:8 69:16	22:24 23:2,16,16	general 20:2
<b>foley</b> 6:15 13:11	97:16 111:19,24		100:15
foley.com 6:17	112:3	25:9,22 27:13 28:12 29:4,16,21	generalizable 26:6
<b>folks</b> 61:17	frame 21:21 63:4	· · · ·	26:16,25 104:1
<b>follow</b> 21:23 48:24	82:19	32:2 33:3,9,19	generally 20:17
70:23 100:24	frames 20:21	34:2,22 35:5,18	23:4 83:19 109:22
114:9,13	francis 7:6	36:22 37:2,2	111:7 119:17
following 16:1	frankly 41:3	38:11 39:14 44:1	<b>geo</b> 96:20 97:9
19:8 73:17,19	fraud 7:4	44:4,9,20 45:13	getting 21:20
81:8	free 14:12 84:24	46:6,14,18 49:12	giacalone 104:14
<b>follows</b> 13:19	126:14 127:20	49:16 50:10,25	give 17:25 22:8
foregoing 124:3,5	frequency 42:15	51:7,12 52:13,21	39:23 40:20
126:13 127:18	43:2 77:4	52:23,24 53:10,25	given 29:2 53:3
<b>forgot</b> 86:20	front 33:14 85:18	55:20,22 56:2,18	60:16 105:18
<b>form</b> 50:4 73:3	100:2 106:9	57:11 58:7 61:17	123:1 124:10
74:9,15 75:12	full 24:22 25:3	64:24 65:21 66:7	gives 48:23
76:16 77:19 78:23	27:18 40:3 53:15	68:17 69:17 71:14	giving 32:3
79:6,14 91:21	53:17	71:23 72:4,7	go 10:13 11:23
92:8,9 93:11,22		73:18 77:24,25	20:5,15 24:9
, , , , , , , , , , , , , , , , , , ,		78:11 81:2,3,17,22	

[go - improved] Page 11

20.25 20.21 22.11	20.10 22 20.11 17	hdma 06.5 11 15	homeland 52:15
29:25 30:21 32:11	29:18,22 30:11,17	hdma 96:5,11,15	
38:22 42:21 63:11	30:24 31:6 32:3	97:24 99:3 100:8	52:21
70:1 77:22 82:25	32:19,24 33:1,4,10	100:14 105:8,13	hope 4:5
90:15 94:22 97:4	33:20 34:12 35:19	105:20 113:7,21	hoped 68:2
97:5 100:13	36:4,13,23 37:19	hdma's 113:10	hospitals 40:24
105:22,25 106:3	38:14,16 39:8,12	head 34:2 98:14	41:10
106:18 108:21	39:17 40:9 42:7,8	117:6	host 54:9 89:6
111:15 114:14	43:1,24 44:11	heading 86:7	hosting 55:8
116:2	45:2,11,23 46:1,11	health 5:7 11:9,11	house 63:20 64:11
<b>goal</b> 55:22	46:15,16,19 48:13	13:23 67:22	housekeeping 15:7
goes 45:7 111:10	48:24 49:8,17,18	101:22,23 113:4	<b>huh</b> 32:14 73:16
<b>going</b> 10:4 24:6,7	50:4,25 51:12	118:9 119:22	human 67:22
24:11,15 33:16	54:19,20 55:2	healthcare 96:16	i
35:13 36:1 41:17	57:10,12 58:4,16	hear 20:2 117:16	<b>i.e.</b> 34:15 77:1,9
51:21 60:21 64:13	58:23,24 59:9,15	<b>heard</b> 101:9	79:21
67:20 69:11 70:5	59:24 60:11 69:18	hearings 19:10	identification
105:10,20,21	69:22 77:8,11	99:8	14:25 15:12 23:9
108:23 109:3	78:3,14 82:4,10	<b>held</b> 2:1 10:21	47:3 52:8 56:9
112:16,20 119:25	83:14 84:3 86:11	43:12 82:22,23	61:11 65:9 80:8
120:3,9,24 122:17	87:12 88:7,23	88:25 104:21	85:7 99:21 104:17
<b>good</b> 10:3 13:25	91:14,25 108:9	108:19 118:8,14	identify 15:14
14:2 20:7,24	110:4,10 111:22	118:20 119:21	23:14 47:11 52:12
70:19,20 71:19	121:25	122:20	56:13 61:15 65:16
93:15	<b>guide</b> 48:3	help 54:22 66:1	117:4
government 18:3	h	71:12,17	illicit 74:4
18:12,17,21 19:15	<b>h.d.</b> 6:8 12:16	helpful 31:20	illinois 3:22 4:19
27:7,12 71:8,13,20	half 17:19 31:8,21	91:19 92:1,7	imagine 103:6
97:15 100:3 111:2	38:17	110:1,8	impact 18:11
grand 3:16	hand 47:8 97:8	helping 20:25	34:17
grant 6:22	handed 80:12	105:14	impacting 35:22
great 24:8 30:6	handing 23:11	hereto 124:16	implementing
31:15 33:15	99:23 104:19	<b>high</b> 42:1	48:5
greater 77:16	handle 76:25	highlighted 45:17	<b>important</b> 73:19
ground 14:7		highlighting 116:3	98:12
<b>group</b> 87:25	handling 22:16	hill 98:16,21 99:6	
<b>groups</b> 76:14 83:6	<b>happen</b> 101:16 <b>hard</b> 14:9	113:23	improper 115:12 improve 65:25
105:18 106:12	hbc 6:19 12:18	himmel 5:21 12:24	71:12 78:2
guess 62:11 71:2		12:24	
77:23	hd 101:24	history 60:23	improved 110:3
<b>guidance</b> 25:11,17	hda 96:15 97:25	hold 23:12	111:9,21 116:13
25:21 27:14 29:1	98:10 99:3 102:12		117:11
	113:7,10,21		

## [inadvertently - july]

inadvertently	inferring 36:4	interacts 28:1	involvement 103:9
41:23	influence 99:13	84:16	irritating 106:13
include 58:15	107:3	interagency 18:8	issuance 24:1
59:24 60:4 63:20	informal 18:6	64:11 67:17	issue 22:8 24:10
included 16:19	information 20:22	interest 18:9	29:21
86:14 125:13	28:3 31:11,23	interested 124:16	issued 23:23 24:7
includes 83:6	50:13,15 54:5	interests 99:5	80:4 81:8 82:10
including 18:4	59:18 60:5 65:24	interfere 10:10	82:11 90:12 91:2
104:23 116:7	83:1 86:19 110:7	interference 10:8	issues 18:8 21:3
incorporated	114:24	intern 7:5	27:25 29:16 35:1
96:20 127:12	informed 71:18	internal 21:11,16	84:13 85:2 89:9
increases 42:3	112:12	24:24 56:1 66:23	99:8 116:13
increasing 42:4	initiated 43:14	interruption	117:11
43:9	initiative 43:14	108:15	j
indiana 5:13 6:11	84:6,13,18 118:3,8	intersect 18:17	
11:13	118:14,21,21	intersection 19:1	<b>j</b> 4:13,17 6:14
indianapolis 6:11	119:8,16,20	interviewed 26:7	janssen 4:2 13:3,6
indicate 32:18	120:20	27:3,7,21 28:13,16	january 63:20
39:18 40:10	input 30:9,23	28:18 97:13 111:1	jeff 7:5 12:22 13:1
indicated 57:8	44:25 87:6 88:3	interviews 28:4	jeffrey 4:8
63:7 82:23 84:15	93:19,24 94:2,6	introducing 14:22	jeffrey.sindelar 4:11
91:24 110:9 122:8	95:1,13,21 101:6	introduction	
indicates 28:12	102:16 103:11	117:8	jennifer 5:8 11:10 job 1:25 73:1
29:4 33:17 61:4	105:16 115:13	investigate 20:10	john 5:2 13:7
66:15	inquiry 100:3	investigates 21:2	john.lavelle 5:5
indicating 35:15	insist 101:12	22:8	johne 7:5 11:24
64:25 67:25	inspections 77:5	investigating	johnson 4:2,2 13:2
125:13	instance 67:13	29:17	13:2,5,6
individual 97:11	instances 19:24	investigation	jones 4:14,18
101:6,11,21,22,23	instructed 14:15	20:18 24:1 25:20	12:21 13:10
101:25 110:2	integrity 71:21	28:10	jonesday 4:16
119:2,18 120:3,25	intensive 40:11	investigations	jonesday.com
individually	<b>inter</b> 31:11	18:21 19:4 22:16	4:20
101:14	interact 111:3	investigative 71:9	joseph 37:6,11,12
individuals 28:18	interacted 109:22	72:1	39:24
industry 88:23	interaction 43:20	invitation 105:20	jr 4:8 5:2
96:21 103:12,18	100:5 101:15	invited 103:10	judge 1:6
104:22 105:17,19	interactions 19:7	involved 67:21	judiciary 8:15
106:11 116:10,12	31:12,20,24	90:20 92:20,25	52:17
industry's 100:15	109:23 110:8	93:14 105:14	july 95:14,22
	111:7		116:21
			110.21

#### [june - management]

june 17:17 57:5,24	knowledge 20.25	62:12 64:17 73:6	located 10:22
	knowledge 28:25		
62:22 63:9 121:24	41:18 113:9,20	73:14 80:24,25	location 101:7
124:23 125:4	known 23:15,16	81:8,12,19 82:20	119:3,10,18
jury 19:14 88:19	43:13	86:3,7 116:2	locations 101:14
101:2 111:16	knows 67:10	121:19 125:19	119:15
justice 3:3,5,9 7:3	kohn 73:14	letters 81:2	long 14:19 40:16
7:4 12:2 50:1	kristina 6:14	level 101:17	longer 68:18 93:14
52:21 67:15 68:3	13:11	lewis 5:3	look 25:16 83:23
68:8	l	liaison 17:22,24	90:16 91:11
justice's 44:21	1 1:24 124:2	18:15 19:1 21:19	110:24
67:1,6	<b>l.p.</b> 1:8,10,12 3:19	21:24 43:10 55:21	looked 49:9
jwicht 5:11	lack 36:4	56:18 61:17 81:3	<b>looking</b> 72:9,13,17
k	lacks 33:25 65:3	85:19 103:8	73:13
<b>kathleen</b> 6:9 12:15	language 59:20	<b>limit</b> 41:21	looks 32:1 87:23
kathleen.matsou	114:23 122:7	limited 43:16	los 4:6
6:12	lardner 6:15 13:12	76:21	lot 82:8
keep 47:7 105:10	large 119:4,17,21	linda 73:14	low 105:25
105:21,24 106:2	largely 19:21	<b>linden</b> 105:23	luxenberg 3:15
kelly 102:11	larger 77:9,15	<b>line</b> 91:11 100:1	11:20,22
kick 20:17		101:18 102:9	m
kind 20:8 43:12	largest 76:25	108:18 120:9	
64:10	lastly 105:23 lavelle 5:2 13:7,7	121:4 125:13	m 5:15,16 6:20 7:4
kinds 21:16	law 75:5	127:7 128:3	mackay 3:20
		list 90:21,22	11:17,17
kmatic 6:17	leaders 116:10	100:19 103:18	madam 125:10
knew 98:15	leadership 116:7	104:8	mail 8:18,21,23
know 28:17 29:11	116:18 117:9,25	listed 97:21,22	9:3,5 80:15 85:15
30:4 34:3 40:21	learn 27:25	121:13 127:7,17	85:17 86:4 100:2
41:16 49:25 75:22	learned 94:20	listening 117:15	101:19 102:10,13
76:1,4 84:25 91:2	left 66:4 77:25	listing 127:7	105:4 107:17
91:13 93:2,8,18	97:8	litigation 1:5	main 4:9 84:15
94:2,6,10,13,14,16	legal 10:25 11:2	125:6 126:3 127:3	maintain 72:23
94:18,19,23 95:4	67:1,7 68:5 69:1,7	little 17:13,25	maintained 72:18
96:11 97:23,24	78:25 79:8,15	57:21 59:2 80:17	majority 92:3,4
98:4 102:22,23	123:4 125:1 128:1	95:10	<b>making</b> 33:12 50:5
103:4,15 104:11	legislative 18:7,13	llc 5:13 11:13	60:12,14 63:2
104:14 106:19,24	legitimate 74:2	llp 2:5 3:20 4:5,9	112:13
107:2,9 112:9	leonhart 116:23	•	malfunction 12:23
114:20 118:11,18	<b>letter</b> 8:10,16 37:7	5:3,9,15,22 6:4,10	management 61:7
118:25 119:11	39:24 40:1 42:10	6:15,21	63:22 67:18 116:8
<b>knowing</b> 110:20	42:24 43:25 44:2	lobbying 99:4	116:10,19 117:9
	44:5 45:14 62:1		117:20
	Voritort Lo		

## [manual - monaghan]

		I	I
manual 8:13 32:7	107:5 110:16	measures 89:22,23	methods 111:4
32:8,10 33:1	113:1,5,13,19	media 10:14 51:23	michael 3:15
47:12 48:1,9 49:8	114:1,21 115:11	52:3 108:25 109:5	11:19
58:24 59:9,10	115:20 117:19	112:22 123:2	michele 116:23
69:23	118:12,19 119:6	meet 54:23	michigan 3:17
manuals 32:24	120:6,11 121:9	meeting 20:17	microphones 10:6
46:19,24 47:14	122:11,15	71:11 88:22 93:3	10:10
manufacturers	<b>matic</b> 6:14 13:11	100:14 103:20	middle 31:17
77:1 98:11	13:11	104:22 105:17	<b>midway</b> 109:15
marc 12:17	matsoukas 6:9	106:15,16,20	midwest 125:17
marcus 6:21,23	12:14,15	117:15	128:1
12:18	matt 4:4 13:4	meetings 93:6,7,25	million 26:13
mariama 3:9 12:3	<b>matter</b> 10:16	103:11 120:4,25	75:24 76:21
mariama.c.spears	16:18 21:14	megan 11:15	milwaukee 6:16
3:12	matters 17:5	meghan 6:3	minutes 113:2
marked 14:23,24	18:10	melanie 3:20	mischaracterizes
15:9,11 23:8,12	matthew 1:18 2:1	11:17	30:20 35:25 49:15
47:2,5 52:7,10	8:2,9 10:15 12:10	melanie.mackay	117:13
56:8,11 61:10,13	13:16 123:1 125:8	3:23	mission 17:7 71:5
65:8,11 80:7 85:6	126:4,9 127:4,13	members 19:5,25	71:23
99:20,24 104:16	128:20	20:9 25:10 98:17	missions 113:14
104:19	maurer 52:15,19	111:20 113:16	misstates 30:19
market 5:4	53:9,24	membership	57:14 122:4
marking 80:5 85:3	maximize 114:24	113:10	mistaken 31:14
mart 12:21 13:10	115:13	memorandum	mmonaghan 6:6
maryland 5:2 13:8	mckesson 6:2	63:21,22 85:20	model 26:15,25
masters 5:9 8:3	11:16 101:25	memory 31:16	moderately 91:18
11:8,8,23 13:24	118:22 119:2,22	mention 54:17	91:25 110:1
14:22 15:1,7,13	mckmdl005380	64:18 83:25	moment 53:12
19:20 20:3 22:14	9:4	mentioned 20:9	54:2 57:8,23
23:10 24:8,19	mckmmdl 99:25	27:11 43:23 55:1	108:22
26:3 31:3 34:4	md 1:5 10:20	57:23 84:4 102:24	moments 90:9
36:11 42:23 47:4	mdl 1:4	113:22 118:2	monaghan 6:3
48:21 49:2,21	mdl2804 9:6	mentions 59:7,8	11:15,15 73:3
50:22 51:18 52:9	mean 20:13 22:2	meridian 6:10	74:9,15 75:12
56:10 57:20 59:22	62:24 63:1 67:5	met 116:10	77:17,19 78:24
61:3,12 65:7,10	98:25	methodical 20:6	79:6,14 91:21
69:14 70:1,13	means 18:1 22:4	20:13	92:9 93:11,22
75:10 76:16 92:8	40:14 42:19 43:2	methodology	94:9 95:3,15
95:8,16,24 96:7,25	63:1 81:4,14	101:5	96:13,23 98:2,9
99:15 103:13,21	03.1 01.4,14	101.3	99:1 102:19
99.13 103:13,21			77.1 102.17
		rol Colutions	1

## [monaghan - office]

104:10,24 106:22	<b>national</b> 1:4 10:17	<b>note</b> 10:6 125:12	74:13 75:9,10
112:6	27:3,12 83:4	<b>noted</b> 54:9,15	76:15,16 77:17,18
monitoring 29:19	97:14 111:3,5	83:24	78:24 79:7 93:22
29:24 30:13 32:20	125:6 126:3 127:3	notes 47:25 54:4	95:8,23,24,25 96:6
33:5 54:7 58:17	nationally 26:4	62:3	96:7,8,12,13,22,23
60:1 72:19,24	97:10	<b>notice</b> 2:10 8:9	96:25 102:6
82:7 86:13 87:14	nationwide 47:20	15:4 50:4 60:2,13	103:13,21 106:21
88:9 89:5 100:21	nature 18:25	63:1 64:3 68:14	106:22 107:5,7
108:12	78:20	notwithstanding	110:16 112:4,6
morgan 5:3	ne 3:6	44:8	113:11,17,24
morganlewis.com	neal 4:13	nstephens 4:16	114:17 115:3,15
5:5	necessarily 30:25	number 20:19	117:12 118:10,16
morning 10:3	36:9 37:1 104:7	39:1 41:11,25	118:23 119:23
13:25 14:2 70:19	119:15	76:11,12 80:17	122:4
70:20,24 82:9	necessary 37:19	83:5 84:23 90:11	objections 14:16
morrissette 3:11	38:24	90:13,24,25 91:16	<b>objective</b> 89:22,23
multiple 93:5	need 38:6 55:14,18	92:10 111:11,25	objects 14:13
multitude 37:21	65:6 76:22 98:13	121:13,14 123:2	obligation 21:8
<b>mute</b> 108:17	110:10	125:7,13	obligations 46:25
<b>mutual</b> 101:24	needed 31:10,23	numbered 99:25	82:7
mwallace 4:7	57:11 58:3 122:2	numbers 77:7,15	observing 35:6
myers 4:5 13:5	negatively 34:17	90:23 91:4 127:7	obstacle 63:15
n	35:21	0	obstacles 63:24
n 3:6 8:1,1 10:1	neil 13:9	o 8:1 10:1 56:18	64:2,18
<b>n.w.</b> 2:6 5:10,16	neither 124:11	o'melveny 4:5	<b>obtain</b> 28:2 29:8
6:5	new 59:23 63:16	13:5	87:6 88:3
nabp 83:22 87:11	63:17,19 116:7,7,8	object 74:9,15	<b>obtained</b> 27:19,20
name 10:24 12:13	116:9,18,19,21	75:12 77:19 78:23	29:5 92:17
70:21 125:6 126:3	117:4,8,9,20	79:6,14,16 91:21	obviously 39:3
126:4,15 127:3,4	nonfederal 28:2,4	92:8,9 93:11 94:9	50:17 60:4 76:20
120:4,13 127:3,4	nonprofit 27:4	95:3,15,16 98:2,9	82:25 98:12
named 102:3	nonprofits 97:15	99:1,15,16,17	occasion 56:3
named 102:3 names 28:17	97:20	, , ,	occurred 93:2
names 20.1/	normal 42:14	102:19 104:10,24	122:1
narcotic 10.25	normai 42:14	111.12	
narcotic 40:25	northern 1:1	111:13	october 104:23
nascsa 105:17		objection 19:16	
nascsa 105:17 106:16,20	northern 1:1	<b>objection</b> 19:16 22:12 25:24 30:19	october 104:23
nascsa 105:17 106:16,20 natalie 3:4 12:8	northern 1:1 10:18 12:6	<b>objection</b> 19:16 22:12 25:24 30:19 33:24 35:24 42:20	october 104:23 offered 31:22 36:3
nascsa 105:17 106:16,20 natalie 3:4 12:8 125:5	northern 1:1 10:18 12:6 northwest 10:23	<b>objection</b> 19:16 22:12 25:24 30:19 33:24 35:24 42:20 43:3 48:17 49:1	october 104:23 offered 31:22 36:3 54:21
nascsa 105:17 106:16,20 natalie 3:4 12:8 125:5 natalie.a.waites	northern 1:1 10:18 12:6 northwest 10:23 notarized 125:14	<b>objection</b> 19:16 22:12 25:24 30:19 33:24 35:24 42:20 43:3 48:17 49:1 49:14 50:11 51:14	october 104:23 offered 31:22 36:3 54:21 offering 77:13
nascsa 105:17 106:16,20 natalie 3:4 12:8 125:5	northern 1:1 10:18 12:6 northwest 10:23 notarized 125:14 notary 124:1,20	<b>objection</b> 19:16 22:12 25:24 30:19 33:24 35:24 42:20 43:3 48:17 49:1	october 104:23 offered 31:22 36:3 54:21 offering 77:13 office 3:10 7:3

[office - person] Page 16

	I		I
27:21 28:13,21	65:19 66:16 89:21	oversight 18:3	pardon 96:20
35:11 37:15 48:2	122:12,14	19:23 20:5 27:22	parent 67:16
63:21 67:1,7,18	operate 45:18	71:18	part 38:7 67:8,8
68:5 69:1,7 71:9	<b>opiate</b> 1:5 10:17	oversupplies 35:4	84:10 103:9
73:23 74:3,7	125:6 126:3 127:3	overview 100:15	107:13 112:2
100:4 109:25	opinion 42:2	oxford 6:21	127:9
110:3 117:9	opportunities	р	participants 93:9
officer 56:17	43:10 77:14	<b>p</b> 5:2 10:1	93:19 97:25
124:2	opportunity 22:9	<b>p.m.</b> 122:24 123:6	103:19
<b>offices</b> 97:12	22:22 40:21 60:10	p.m. 122.24 123.0 page 8:2 15:22	participate 15:16
official 126:15	60:15 89:3 90:7	24:20,21 27:18	15:17
127:21	117:16	30:4,5 31:13	participated 96:4
officials 27:22	order 29:19,24	32:12,13 33:16	100:9 104:8
28:14,19,24 97:14	33:5 37:24 39:18	34:5 39:23,25	participating
110:9 111:1	40:10 42:8,13,13	40:1 44:14,23	93:24
oftentimes 14:15	42:15 49:19 50:2	45:5 46:5 47:25	participation 94:8
20:21	55:12,16 57:12	53:9 57:17 61:25	particular 21:8
<b>oh</b> 35:10 78:7,12	59:13,16 72:19,24	66:11,12 71:1,3,5	37:3 108:3
93:21 97:22	82:7 86:13 100:21	73:5,13 74:17,19	parties 2:11 10:13
<b>ohio</b> 1:1,10,12	108:12 122:2	74:20 77:22 78:5	124:12,15
4:10 10:19 12:7	ordered 34:15	78:6,7 80:23	pat 102:11
125:2	36:16	81:24 82:3 85:18	patient 35:22
okay 14:19 15:21	orders 30:13	86:6 89:12 92:14	patients 34:18
17:8,16 24:8	32:20 39:17 40:9		41:8
26:22 30:6 31:4	45:11,19 54:8	97:5,6 99:25 108:14 116:1	patrick 4:17 12:20
33:15 37:2 40:2	58:15 62:5,19		pattern 42:15 43:2
44:1 49:6 51:18	63:14 66:22 72:14	125:13,15 127:7	pbeisell 4:20
53:6 55:15 63:23	72:23 87:14 88:10	128:3	pending 61:6
69:15 70:25 73:20	88:24 89:6 116:25	pages 48:10	pennsylvania 5:4
74:21 78:9 81:23	organization	palo 4:15	5:23 6:22
91:16 105:12	67:16	paragraph 24:22	people 71:14
106:4 107:16	organizations 27:4	25:3 27:18 31:17	93:13 94:16
111:17	outcome 124:17	32:17 34:6 40:3	perceived 106:8
omb 67:19,20	outlined 82:20	46:6 53:14,15,16	percent 43:18
omm.com 4:7	84:14 89:18	53:17 73:9,12	109:24
once 21:23 51:6	outset 39:5	81:11 82:21 83:3	performance
ongoing 54:5	outside 19:19	85:25 86:16 88:13	71:12
87:12 88:7	overages 42:1	92:17 100:7,23	<b>period</b> 20:23
op 1:9,11,13	overall 106:6	109:16 110:24	persistent 20:22
open 31:9,19 39:2	oversees 68:6	111:10 116:4,5	person 37:16
39:3 49:20 51:16		paragraphs 86:17	43:21,21 77:3,13
27.2 .7.20 21.10			.5.21,21 / / .5,15
	37 ·4 4 T		

#### [person - production]

117:4 121:1	physicians 32:4	populations 26:2	63:14 106:16,19
personal 28:25	pick 10:7	portion 39:11	presentations
personally 92:20	<b>piggins</b> 3:15 11:19	75:18 76:24	83:19,20 85:1
126:11 127:15	11:19	portions 77:8	<b>presently</b> 26:12,19
perspectives 27:14	pittsburgh 5:23	position 16:22	prevent 100:16
28:3	6:22	37:18,23 38:8	preventing 74:2
pertain 48:6 73:25	<b>place</b> 10:9,12 38:2	possible 113:2	previous 58:8
pertaining 48:20	60:13 67:14 68:10	<b>potential</b> 63:15,23	85:25 86:21
51:3	68:13,14	64:2 97:22	previously 33:8
pertains 43:6 75:3	<b>plain</b> 59:11 114:22	potentially 106:13	56:14 94:17
<b>pharma</b> 1:8,10,12	122:7	powerpoint 83:20	primary 74:25
3:19	plaintiffs 3:13	practice 48:25	<b>prior</b> 17:8,19,20
pharmaceutical	11:20,22 70:17,22	practitioner 26:12	24:1 37:4 52:23
75:3	114:2 121:11	46:1 59:10	57:15 68:11,13,15
pharmaceuticals	<b>plan</b> 45:22	practitioner's 32:7	
4:3 13:3	planned 59:15	practitioners	prioritize 76:23
pharmacies 25:12	planning 101:4	25:14,15,18 26:9	priority 50:3
25:18 26:8,11,11	<b>plans</b> 54:9,18 55:1	26:24 32:25 34:16	117:21 118:1
26:23 32:3 33:23	59:8 89:6	46:20,24 54:21	private 10:7
34:16,17 35:22	<b>play</b> 60:25	59:1 69:24 97:13	privileged 50:13
40:24 41:9,12	<b>please</b> 10:6,9 11:7	preceding 86:17	50:15 59:18 69:9
47:20 54:21 75:16	12:13 13:14 30:6	86:19 87:24	<b>privy</b> 103:17
76:2,10,12 77:10	32:15 46:7 54:13	predecisional 59:3	probably 38:3
78:21 79:4,11,23	71:2,6 73:9,22	<b>prefer</b> 101:12	81:15 93:5 95:10
97:12 110:2	88:19 100:7 101:1	preliminary 61:5	102:25
pharmacist 32:7	105:5,11 108:22	preparation 53:7	probing 120:21
47:12 59:10	109:20 110:25	85:10	procedure 126:5
pharmacist's 8:13	125:11,11	prepared 48:1	127:5
pharmacists 32:24	plus 119:14	120:13	procedures 60:14
46:20,24 48:3,13	point 26:10 38:21	preparing 101:3	proceed 13:21
58:25 69:24	38:24 39:10,21	prepping 18:5	14:17 24:18 52:6
pharmacy 34:24	44:12 53:14 58:5	19:12	70:12 109:8
35:11,14,16 36:21	66:14 119:1,12	prescribers 26:13	112:25
36:21 40:18 41:5	policies 71:16	77:10	proceeding 123:5
41:6 46:1 48:6	policy 16:24 17:3	prescribing 83:10	process 63:18 67:9
83:5 97:12 110:3	17:5,9 67:1,7 68:6	prescription 1:4	69:12 92:21,25
philadelphia 5:4	69:1,7 71:18	10:17 27:24 125:6	114:15
phone 108:15,17	polster 1:7	126:3 127:3	processes 21:11,16
125:3	<b>population</b> 41:7	prescriptions 41:8	<b>production</b> 125:15
phones 10:9	43:17,18 83:8	<b>present</b> 2:10 7:1 11:4 26:13 38:25	125:17,22
	90:19,22 91:7	11.4 20.15 36.23	

#### [profession-recommendations]

profession 48:6,16	127:15,23 128:23	<b>questions</b> 14:11,12	reads 71:5 86:16
professional 48:25	publication 37:4	20:20 21:21 31:10	ready 63:2
profile 105:25	38:3 63:15 64:4	39:1,2,4 70:3,14	real 14:7 24:9 70:2
profiles 41:14	68:11,14,15	70:24 75:15 80:3	really 20:7 59:4
program 17:7,7,17	publications 32:8	82:8 89:8 94:3,5	61:1 93:15 103:8
21:25 37:17 117:5	publish 67:11	100:19,24 101:5	reason 83:25
programs 40:25	68:19	102:16 112:15	93:12 98:5 125:14
71:15	published 50:5	113:7 114:4,9,10	127:8 128:3
promulgation	51:7 62:17,20,24	114:13,15 120:1	reasonable 64:14
63:17	63:3,7,9 64:21	122:15	112:11
proposals 18:7	65:1 69:19,22	quick 14:7 24:9	recall 75:20 80:20
proposed 50:4	83:2	51:19 70:2	84:8 107:21 114:5
61:5 63:2	pulling 100:10	quite 41:3	114:11
proposing 58:23	purchase 40:18	quote 35:8 63:15	receipt 125:18
protocols 100:22	purdue 1:8,10,12	111:11	receive 84:25
provide 39:16	3:19 11:18 106:12	quoting 35:9	received 39:7 90:7
40:8 42:7 44:10	purposes 104:2	r	101:7
45:10 46:10 47:17	pursuant 2:10	r 3:14 10:1	recess 24:14 51:25
55:18 57:12 58:3	<b>push</b> 36:2	raise 59:4	70:8 109:2 112:19
69:17 83:14 86:10	<b>put</b> 51:4 111:10	raise 39.4	recognition
87:12 88:7 108:8	q	ran 37:16	116:20
provided 37:2,3	-	1an 57.10	15.4
	qualifier 64.8	rannazzisi 37.6 11	recognize 15:4
39:9 42:25 47:15	qualifier 64:8	rannazzisi 37:6,11	recognize 13.4
39:9 42:25 47:15 47:19 49:22 50:23	qualify 43:5	37:12 39:25	
39:9 42:25 47:15	qualify 43:5 quarter 62:21	37:12 39:25 rbarnes 6:23	recollection 55:4
39:9 42:25 47:15 47:19 49:22 50:23	qualify 43:5 quarter 62:21 63:8 64:6 65:1	37:12 39:25 rbarnes 6:23 reached 27:13	recollection 55:4 recommend 73:10 recommendation 22:1,3 30:1,2,8,15
39:9 42:25 47:15 47:19 49:22 50:23 51:11 52:14 54:5 64:24 83:1 85:25 89:2 100:18	qualify 43:5 quarter 62:21 63:8 64:6 65:1 67:2 68:1,24 69:4	37:12 39:25 rbarnes 6:23 reached 27:13 read 28:6 29:25	recollection 55:4 recommend 73:10 recommendation 22:1,3 30:1,2,8,15 33:7,13 44:25
39:9 42:25 47:15 47:19 49:22 50:23 51:11 52:14 54:5 64:24 83:1 85:25 89:2 100:18 103:24 105:15	qualify 43:5 quarter 62:21 63:8 64:6 65:1 67:2 68:1,24 69:4 69:15	37:12 39:25 rbarnes 6:23 reached 27:13 read 28:6 29:25 30:22 31:25 32:15	recollection 55:4 recommend 73:10 recommendation 22:1,3 30:1,2,8,15 33:7,13 44:25 49:20 50:9 51:8
39:9 42:25 47:15 47:19 49:22 50:23 51:11 52:14 54:5 64:24 83:1 85:25 89:2 100:18 103:24 105:15 120:16	qualify 43:5 quarter 62:21 63:8 64:6 65:1 67:2 68:1,24 69:4 69:15 question 14:14,17	37:12 39:25 rbarnes 6:23 reached 27:13 read 28:6 29:25 30:22 31:25 32:15 34:10 40:5 46:3,7	recollection 55:4 recommend 73:10 recommendation 22:1,3 30:1,2,8,15 33:7,13 44:25 49:20 50:9 51:8 51:17 53:11 54:1
39:9 42:25 47:15 47:19 49:22 50:23 51:11 52:14 54:5 64:24 83:1 85:25 89:2 100:18 103:24 105:15 120:16 provides 48:12	qualify 43:5 quarter 62:21 63:8 64:6 65:1 67:2 68:1,24 69:4 69:15 question 14:14,17 31:19 34:3 39:7	37:12 39:25 rbarnes 6:23 reached 27:13 read 28:6 29:25 30:22 31:25 32:15 34:10 40:5 46:3,7 48:7 49:3 54:11	recollection 55:4 recommend 73:10 recommendation 22:1,3 30:1,2,8,15 33:7,13 44:25 49:20 50:9 51:8 51:17 53:11 54:1 55:7,13,17 56:4
39:9 42:25 47:15 47:19 49:22 50:23 51:11 52:14 54:5 64:24 83:1 85:25 89:2 100:18 103:24 105:15 120:16 provides 48:12 71:16	qualify 43:5 quarter 62:21 63:8 64:6 65:1 67:2 68:1,24 69:4 69:15 question 14:14,17	37:12 39:25 rbarnes 6:23 reached 27:13 read 28:6 29:25 30:22 31:25 32:15 34:10 40:5 46:3,7 48:7 49:3 54:11 54:13 58:19 67:3	recollection 55:4 recommend 73:10 recommendation 22:1,3 30:1,2,8,15 33:7,13 44:25 49:20 50:9 51:8 51:17 53:11 54:1 55:7,13,17 56:4 57:9,13,25 58:8,12
39:9 42:25 47:15 47:19 49:22 50:23 51:11 52:14 54:5 64:24 83:1 85:25 89:2 100:18 103:24 105:15 120:16 provides 48:12 71:16 providing 18:6	qualify 43:5 quarter 62:21 63:8 64:6 65:1 67:2 68:1,24 69:4 69:15 question 14:14,17 31:19 34:3 39:7 44:3 53:23 57:21 59:5 64:13 69:13	37:12 39:25 rbarnes 6:23 reached 27:13 read 28:6 29:25 30:22 31:25 32:15 34:10 40:5 46:3,7 48:7 49:3 54:11	recollection 55:4 recommend 73:10 recommendation 22:1,3 30:1,2,8,15 33:7,13 44:25 49:20 50:9 51:8 51:17 53:11 54:1 55:7,13,17 56:4 57:9,13,25 58:8,12 58:22 59:14 62:2
39:9 42:25 47:15 47:19 49:22 50:23 51:11 52:14 54:5 64:24 83:1 85:25 89:2 100:18 103:24 105:15 120:16 provides 48:12 71:16 providing 18:6 39:15 40:7 45:9	qualify 43:5 quarter 62:21 63:8 64:6 65:1 67:2 68:1,24 69:4 69:15 question 14:14,17 31:19 34:3 39:7 44:3 53:23 57:21 59:5 64:13 69:13 89:21 91:24 94:11	37:12 39:25 rbarnes 6:23 reached 27:13 read 28:6 29:25 30:22 31:25 32:15 34:10 40:5 46:3,7 48:7 49:3 54:11 54:13 58:19 67:3 71:6 73:8,21 87:25 88:18 92:15	recollection 55:4 recommend 73:10 recommendation 22:1,3 30:1,2,8,15 33:7,13 44:25 49:20 50:9 51:8 51:17 53:11 54:1 55:7,13,17 56:4 57:9,13,25 58:8,12 58:22 59:14 62:2 63:13 66:5,9,16
39:9 42:25 47:15 47:19 49:22 50:23 51:11 52:14 54:5 64:24 83:1 85:25 89:2 100:18 103:24 105:15 120:16 provides 48:12 71:16 providing 18:6 39:15 40:7 45:9 52:22 57:3 77:11	qualify 43:5 quarter 62:21 63:8 64:6 65:1 67:2 68:1,24 69:4 69:15 question 14:14,17 31:19 34:3 39:7 44:3 53:23 57:21 59:5 64:13 69:13	37:12 39:25 rbarnes 6:23 reached 27:13 read 28:6 29:25 30:22 31:25 32:15 34:10 40:5 46:3,7 48:7 49:3 54:11 54:13 58:19 67:3 71:6 73:8,21 87:25 88:18 92:15 100:6 101:1 105:3	recollection 55:4 recommend 73:10 recommendation 22:1,3 30:1,2,8,15 33:7,13 44:25 49:20 50:9 51:8 51:17 53:11 54:1 55:7,13,17 56:4 57:9,13,25 58:8,12 58:22 59:14 62:2 63:13 66:5,9,16 82:4 83:13 86:10
39:9 42:25 47:15 47:19 49:22 50:23 51:11 52:14 54:5 64:24 83:1 85:25 89:2 100:18 103:24 105:15 120:16 provides 48:12 71:16 providing 18:6 39:15 40:7 45:9 52:22 57:3 77:11 88:23	qualify 43:5 quarter 62:21 63:8 64:6 65:1 67:2 68:1,24 69:4 69:15 question 14:14,17 31:19 34:3 39:7 44:3 53:23 57:21 59:5 64:13 69:13 89:21 91:24 94:11 94:15,24 95:5 97:2 110:22	37:12 39:25 rbarnes 6:23 reached 27:13 read 28:6 29:25 30:22 31:25 32:15 34:10 40:5 46:3,7 48:7 49:3 54:11 54:13 58:19 67:3 71:6 73:8,21 87:25 88:18 92:15	recollection 55:4 recommend 73:10 recommendation 22:1,3 30:1,2,8,15 33:7,13 44:25 49:20 50:9 51:8 51:17 53:11 54:1 55:7,13,17 56:4 57:9,13,25 58:8,12 58:22 59:14 62:2 63:13 66:5,9,16 82:4 83:13 86:10 86:18,22 87:2,5,19
39:9 42:25 47:15 47:19 49:22 50:23 51:11 52:14 54:5 64:24 83:1 85:25 89:2 100:18 103:24 105:15 120:16 provides 48:12 71:16 providing 18:6 39:15 40:7 45:9 52:22 57:3 77:11 88:23 provisions 73:25	qualify 43:5 quarter 62:21 63:8 64:6 65:1 67:2 68:1,24 69:4 69:15 question 14:14,17 31:19 34:3 39:7 44:3 53:23 57:21 59:5 64:13 69:13 89:21 91:24 94:11 94:15,24 95:5	37:12 39:25 rbarnes 6:23 reached 27:13 read 28:6 29:25 30:22 31:25 32:15 34:10 40:5 46:3,7 48:7 49:3 54:11 54:13 58:19 67:3 71:6 73:8,21 87:25 88:18 92:15 100:6 101:1 105:3 106:5 109:20	recollection 55:4 recommend 73:10 recommendation 22:1,3 30:1,2,8,15 33:7,13 44:25 49:20 50:9 51:8 51:17 53:11 54:1 55:7,13,17 56:4 57:9,13,25 58:8,12 58:22 59:14 62:2 63:13 66:5,9,16 82:4 83:13 86:10 86:18,22 87:2,5,19 88:2 89:17 108:5
39:9 42:25 47:15 47:19 49:22 50:23 51:11 52:14 54:5 64:24 83:1 85:25 89:2 100:18 103:24 105:15 120:16 provides 48:12 71:16 providing 18:6 39:15 40:7 45:9 52:22 57:3 77:11 88:23 provisions 73:25 provosnik 121:3	qualify 43:5 quarter 62:21 63:8 64:6 65:1 67:2 68:1,24 69:4 69:15 question 14:14,17 31:19 34:3 39:7 44:3 53:23 57:21 59:5 64:13 69:13 89:21 91:24 94:11 94:15,24 95:5 97:2 110:22 111:24 115:6,7,19 119:11 120:8	37:12 39:25 rbarnes 6:23 reached 27:13 read 28:6 29:25 30:22 31:25 32:15 34:10 40:5 46:3,7 48:7 49:3 54:11 54:13 58:19 67:3 71:6 73:8,21 87:25 88:18 92:15 100:6 101:1 105:3 106:5 109:20 110:25 111:15 116:14 122:9	recollection 55:4 recommend 73:10 recommendation 22:1,3 30:1,2,8,15 33:7,13 44:25 49:20 50:9 51:8 51:17 53:11 54:1 55:7,13,17 56:4 57:9,13,25 58:8,12 58:22 59:14 62:2 63:13 66:5,9,16 82:4 83:13 86:10 86:18,22 87:2,5,19 88:2 89:17 108:5 108:7 110:13
39:9 42:25 47:15 47:19 49:22 50:23 51:11 52:14 54:5 64:24 83:1 85:25 89:2 100:18 103:24 105:15 120:16 provides 48:12 71:16 providing 18:6 39:15 40:7 45:9 52:22 57:3 77:11 88:23 provisions 73:25 provosnik 121:3 public 20:2 26:16	qualify 43:5 quarter 62:21 63:8 64:6 65:1 67:2 68:1,24 69:4 69:15 question 14:14,17 31:19 34:3 39:7 44:3 53:23 57:21 59:5 64:13 69:13 89:21 91:24 94:11 94:15,24 95:5 97:2 110:22 111:24 115:6,7,19 119:11 120:8 121:6,10	37:12 39:25 rbarnes 6:23 reached 27:13 read 28:6 29:25 30:22 31:25 32:15 34:10 40:5 46:3,7 48:7 49:3 54:11 54:13 58:19 67:3 71:6 73:8,21 87:25 88:18 92:15 100:6 101:1 105:3 106:5 109:20 110:25 111:15	recollection 55:4 recommend 73:10 recommendation 22:1,3 30:1,2,8,15 33:7,13 44:25 49:20 50:9 51:8 51:17 53:11 54:1 55:7,13,17 56:4 57:9,13,25 58:8,12 58:22 59:14 62:2 63:13 66:5,9,16 82:4 83:13 86:10 86:18,22 87:2,5,19 88:2 89:17 108:5 108:7 110:13 112:2 121:16,19
39:9 42:25 47:15 47:19 49:22 50:23 51:11 52:14 54:5 64:24 83:1 85:25 89:2 100:18 103:24 105:15 120:16 provides 48:12 71:16 providing 18:6 39:15 40:7 45:9 52:22 57:3 77:11 88:23 provisions 73:25 provosnik 121:3 public 20:2 26:16 60:6,7,14 63:3	qualify 43:5 quarter 62:21 63:8 64:6 65:1 67:2 68:1,24 69:4 69:15 question 14:14,17 31:19 34:3 39:7 44:3 53:23 57:21 59:5 64:13 69:13 89:21 91:24 94:11 94:15,24 95:5 97:2 110:22 111:24 115:6,7,19 119:11 120:8	37:12 39:25 rbarnes 6:23 reached 27:13 read 28:6 29:25 30:22 31:25 32:15 34:10 40:5 46:3,7 48:7 49:3 54:11 54:13 58:19 67:3 71:6 73:8,21 87:25 88:18 92:15 100:6 101:1 105:3 106:5 109:20 110:25 111:15 116:14 122:9 126:5,6,12 127:5,6 127:17	recollection 55:4 recommend 73:10 recommendation 22:1,3 30:1,2,8,15 33:7,13 44:25 49:20 50:9 51:8 51:17 53:11 54:1 55:7,13,17 56:4 57:9,13,25 58:8,12 58:22 59:14 62:2 63:13 66:5,9,16 82:4 83:13 86:10 86:18,22 87:2,5,19 88:2 89:17 108:5 108:7 110:13 112:2 121:16,19 121:22 122:3
39:9 42:25 47:15 47:19 49:22 50:23 51:11 52:14 54:5 64:24 83:1 85:25 89:2 100:18 103:24 105:15 120:16 provides 48:12 71:16 providing 18:6 39:15 40:7 45:9 52:22 57:3 77:11 88:23 provisions 73:25 provosnik 121:3 public 20:2 26:16 60:6,7,14 63:3 67:10 71:15 124:1	qualify 43:5 quarter 62:21 63:8 64:6 65:1 67:2 68:1,24 69:4 69:15 question 14:14,17 31:19 34:3 39:7 44:3 53:23 57:21 59:5 64:13 69:13 89:21 91:24 94:11 94:15,24 95:5 97:2 110:22 111:24 115:6,7,19 119:11 120:8 121:6,10 questioning 114:3 120:10 121:4	37:12 39:25 rbarnes 6:23 reached 27:13 read 28:6 29:25 30:22 31:25 32:15 34:10 40:5 46:3,7 48:7 49:3 54:11 54:13 58:19 67:3 71:6 73:8,21 87:25 88:18 92:15 100:6 101:1 105:3 106:5 109:20 110:25 111:15 116:14 122:9 126:5,6,12 127:5,6	recollection 55:4 recommend 73:10 recommendation 22:1,3 30:1,2,8,15 33:7,13 44:25 49:20 50:9 51:8 51:17 53:11 54:1 55:7,13,17 56:4 57:9,13,25 58:8,12 58:22 59:14 62:2 63:13 66:5,9,16 82:4 83:13 86:10 86:18,22 87:2,5,19 88:2 89:17 108:5 108:7 110:13 112:2 121:16,19 121:22 122:3 recommendations
39:9 42:25 47:15 47:19 49:22 50:23 51:11 52:14 54:5 64:24 83:1 85:25 89:2 100:18 103:24 105:15 120:16 provides 48:12 71:16 providing 18:6 39:15 40:7 45:9 52:22 57:3 77:11 88:23 provisions 73:25 provosnik 121:3 public 20:2 26:16 60:6,7,14 63:3	qualify 43:5 quarter 62:21 63:8 64:6 65:1 67:2 68:1,24 69:4 69:15 question 14:14,17 31:19 34:3 39:7 44:3 53:23 57:21 59:5 64:13 69:13 89:21 91:24 94:11 94:15,24 95:5 97:2 110:22 111:24 115:6,7,19 119:11 120:8 121:6,10 questioning 114:3	37:12 39:25 rbarnes 6:23 reached 27:13 read 28:6 29:25 30:22 31:25 32:15 34:10 40:5 46:3,7 48:7 49:3 54:11 54:13 58:19 67:3 71:6 73:8,21 87:25 88:18 92:15 100:6 101:1 105:3 106:5 109:20 110:25 111:15 116:14 122:9 126:5,6,12 127:5,6 127:17 reading 30:4	recollection 55:4 recommend 73:10 recommendation 22:1,3 30:1,2,8,15 33:7,13 44:25 49:20 50:9 51:8 51:17 53:11 54:1 55:7,13,17 56:4 57:9,13,25 58:8,12 58:22 59:14 62:2 63:13 66:5,9,16 82:4 83:13 86:10 86:18,22 87:2,5,19 88:2 89:17 108:5 108:7 110:13 112:2 121:16,19 121:22 122:3

#### [recommendations-report]

21 17 22 22 7	6 1 565	75 22 25 76 14 21	10414
21:17,23 22:5	referenced 56:5	75:22,25 76:14,21	relative 124:14
29:22 52:24 55:23	116:18 120:19	77:6,15 78:3,14	relatively 55:24
56:21 57:4,6	126:11 127:15	79:21 89:4 90:20	release 19:8
65:19,22 71:17	referred 29:10	91:23 95:1,18,22	releasing 22:10
108:2,4,5 110:21	56:25	99:14 102:3	relevant 17:6
recommended	referring 15:23	104:23 107:3	reliability 71:21
49:12,16 51:12	16:5,14 39:3	108:9,10 109:21	rely 77:10
69:17	44:13 55:5,19	111:22 118:5	remain 50:20
recommending	65:21	registration	remaining 49:20
33:13 46:15 55:6	reflected 71:20	103:25 119:3	remains 51:16
recommends	reflecting 114:4	registrations	remarks 84:1
77:24 78:1,11	115:22	108:9 119:5	remember 38:24
reconcile 93:16	reflects 89:25	regs 60:25	remotely 11:5
record 10:4,13	<b>reg</b> 51:6 68:6	regular 32:21	12:13
11:7 14:16 24:9	regarding 30:11	55:21	renee 7:2 12:5
24:12,16 32:15	32:19 33:4 45:24	regularly 87:10	repeat 36:18 44:3
40:5 51:22 52:2	52:23 58:15,16	88:6	45:7 95:19 97:1
70:2,6,10 80:5,18	59:25 62:2,4,19	regulation 37:24	rephrase 77:20
85:4 92:16 99:23	66:21 87:13 88:8	42:9,12,18 51:6	<b>report</b> 8:11 17:4
104:20 107:20	96:5 100:4 108:10	59:23 62:4,16,19	21:22 22:10,25
108:20,21,24	109:12 121:6	62:24 63:6,19	23:4,5,15,17,21,23
109:4 112:17,21	register 50:5 60:2	64:25 66:21 67:6	24:2,20 26:19
121:18 122:18,20	62:17,20,25 63:10	67:24 68:19,25	27:2,18 28:12
122:22,24 124:10	64:5 68:12,20	69:6,19	29:10 30:5,15
127:9	69:20	regulations 45:17	31:4,14 32:6,12
recorded 10:15	registered 32:10	45:25 48:5,15,19	34:5 37:4,13
recording 10:12	40:24 60:8 84:21	48:23 58:14 59:12	39:25 44:1,4,9
recordkeeping	84:24 91:7 97:11	59:16,21 60:3,17	47:7 49:7 51:1
79:20	101:7,14	61:2,5 63:18 79:5	53:6,12,22 54:1
recounting 55:25	registrant 26:2	regulatory 25:13	56:24 57:2,4 59:6
red 83:10	38:5 43:17,18	46:25 50:3 57:18	61:20 65:20,23
reduced 124:8	77:9 79:18 83:8	60:23 67:9	72:7,22 73:6,18
reducing 74:4	91:6 110:10 117:2	relate 72:24	74:18 78:13,18
reed 5:22	119:10	<b>related</b> 57:9 83:10	80:2,4 81:6,9
reedsmith.com	registrants 25:22	88:24 124:11	82:11 89:14 90:12
5:24	27:11,15,23 28:1	relates 1:6 111:20	90:14 91:1 94:21
refer 16:12,13	29:2 38:12 45:22	<b>relating</b> 15:23,24	95:13,21 96:5,19
26:20 122:6	45:24 46:2,13	22:17 29:18,23	100:10 103:2
reference 74:23	47:15 48:20 49:10	65:23 66:10	107:4 108:1,3
81:11 125:7 126:2	51:4 65:24 72:9	113:15	109:12 110:14
127:2	72:14,18,22 75:8		116:17 120:16,18

[report - russo] Page 20

121:7,12	requests 19:25	71:11 78:4,15	revising 58:14
reported 1:24	88:1	82:15 86:12 87:13	62:8
66:20,24 72:14	require 45:17	88:9 89:5 108:11	revision 62:18
87:4	77:16	110:5	right 22:22 23:1
reporter 11:1	required 49:19	responsibility	27:1 36:24 38:19
13:14 14:9 126:7	125:25	17:2 27:23 74:7	44:2,11 45:3,11,19
reporting 29:24	requirements 41:6	78:20 111:21	46:21 62:9 64:21
30:13 32:20 33:5	79:12,19,20,22	responsible 45:23	66:6,12 69:1 72:2
50:15 52:20 53:3	resources 76:21	72:4 73:24 75:1	76:6 78:18 81:5
60:1 79:12,19	76:23	, _ , , , , , , , , , , , , , , , , , ,	87:16 88:16 89:19
82:7 87:14 88:9		responsiveness 114:25 115:14	90:2 91:14
89:6	respect 26:25 73:17 86:12 91:13	restrict 63:17	
	113:15		rite 5:2 13:8 road 4:15
reports 15:25 16:1		restricting 35:7,20 resulted 36:5	
18:21 19:9,25	respective 2:11		rob 104:14
52:24 57:1 58:9	respond 21:8 22:9	117:6,10	robert 6:20 12:17
65:19	22:22,25 50:13,14	resulting 35:19	role 17:8,9 18:2,15
represent 43:17	69:9 90:7 91:23	results 28:4 36:20	18:25 19:6,12,23
70:22	101:11	retail 47:20	20:5 54:23 74:12
representative	responded 31:9	retained 123:3	74:25
26:4 97:10 101:20	37:6 44:1 91:10	retired 94:17	roles 17:11 18:4
113:16	respondents 35:10	116:24	30:12 54:6 58:16
representatives	38:15	retiring 117:7	59:25 65:25 78:3
98:18,22 103:12	responding 21:17	returned 125:18	78:15 86:12 87:13
103:19 104:22	44:20 69:13	reverse 88:25 89:7	88:8 89:4 108:11
105:19	response 22:24,25	review 25:10	110:5 111:20
representing	23:2 31:19 35:5	50:20 53:6 55:25	<b>room</b> 3:6 11:4
30:10 45:1 82:6	44:21 57:17 58:11	61:6 64:3 66:23	rosenberg 117:25
83:7 87:7 88:4	58:21 62:2 63:12	67:20 125:12	rosenberg's
89:23 90:4 108:10	80:1 81:12,16	126:1 127:1	116:25
represents 57:17	82:1,2,3 84:14	reviewed 29:5,15	routine 55:24
65:18 98:10 99:4	86:1,9 87:4 89:18	61:23 62:3 66:20	56:19 77:4
reps 106:15,19	101:13 116:5,16	80:16 85:10	ruiz 5:15 11:12,12
request 20:10	120:15 121:18	121:12	rule 50:5 60:12,13
86:22 87:1,5,19,22	responses 20:20	reviewing 58:14	63:2 66:23,25
88:23 121:22	21:1,20 32:18	62:8 80:20	68:15
127:9,11	39:7 90:1,5 91:12	reviews 67:21	rules 14:8 48:19
requested 19:5,5	120:17	revise 59:15,21	126:5 127:5
requesters 8:12	responsibilities	60:3	<b>run</b> 117:5
requesting 86:18	17:22,25 18:16	revised 60:18 61:1	russo 1:24 7:6
114:24	25:13 30:12 54:7	62:3,16 63:6	10:24 11:2 124:2
	54:23 58:17 59:25	66:21,22 69:19	

[rx - sorry] Page 21

rx 5:13 11:14	07.6 100.7 105.16	106:5	sided 65:12
rzodkiewicz 7:5	97:6 100:7 105:16		
	110:24 116:1,5 section 7:4 15:22	<b>separate</b> 31:1 84:13	signature 124:19 125:14
11:24,24			
S	16:20 17:20,21	september 81:13	signed 126:13
s 8:1 10:1 125:15	32:12 44:19 71:4	series 102:25	127:18
127:8,8 128:3	81:3,24 82:1,13	seriously 21:5	<b>signing</b> 125:19
sample 104:2	98:15 103:8	service 12:18	signs 83:10
sampling 101:4	security 52:15,21	45:22	similar 54:20
satisfaction 22:5	see 16:2 25:1 34:8	services 5:14	61:22 81:21,22
111:6	38:6 44:17 47:23	11:14 67:23	87:23
satisfied 109:23	48:10 65:6 83:24	serving 17:18	simply 120:21
111:8	90:3 91:12 94:22	session 117:15	sincerely 125:21
satisfy 59:13 122:2	97:17 101:20	set 34:24 40:20	sindelar 4:8 13:1,1
saying 19:18 43:5	109:18	setting 33:21	sir 125:10
90:4	seek 20:20	34:13 35:19 36:5	site 32:9 65:18
says 16:4 31:18	seeking 59:20	36:14 41:21	66:15 77:12 83:2
44:14 45:16,21	100:20 115:2	<b>shapira</b> 6:21 12:18	107:25 109:12
59:20 61:9 97:9	seeks 60:2	shapira.com 6:23	122:9
scheduled 87:10	seen 15:2,18 23:17	sheer 77:7	sitting 63:6
88:6	91:5	<b>sheet</b> 125:13 127:7	situation 41:24
scope 19:16,18,19	selected 94:7	127:10,18 128:1	size 42:13,19 43:2
42:20 43:3 48:17	sell 33:22 41:1	<b>short</b> 24:14 39:15	91:6
49:1 60:20 73:2	senate 8:15 52:15	40:7 45:8 51:25	<b>slightly</b> 43:19 92:6
74:14 75:10,11	<b>send</b> 67:5	70:8 109:2 112:19	<b>smith</b> 5:22 6:8
76:15 77:18 78:23	sending 66:25	shortage 41:23	12:16 35:24
78:24 79:7,15,16	85:19 101:13	shorthand 19:18	101:22,24 118:10
95:24 96:7,12,13	senior 16:24 17:3	124:7	<b>sole</b> 21:19
96:24 99:2,16,17	17:9 28:19,24	shortly 19:10	<b>solicit</b> 30:8,23
102:6 106:21	sensitive 10:7	55:11,16 116:22	44:25
107:6 113:11,17	sent 26:7 39:6,25	<b>show</b> 34:12 36:14	<b>solicited</b> 93:4 95:1
113:24 114:18	68:2 69:6 81:17	38:15 116:2	95:12,20 103:11
	sentence 24:23	showing 15:9	soliciting 115:13
115:4 118:10,16 118:23 119:24	33:17 34:10,21	35:17,17 47:5	solomon 7:6
seal 126:15 127:21	36:19 40:4 46:7	52:10 56:11 61:13	solutions 10:25
sear 120:13 127:21 second 23:12	53:19 59:12 61:4	65:11 106:14	11:3 123:4 125:1
24:22 25:2 32:16	73:8,11 77:25	<b>shown</b> 114:3	128:1
	92:16 97:8 100:6	115:21 125:16	somebody 101:23
34:6 39:23 40:3	109:16 110:12	sic 95:1 97:9	101:24,24
44:24 47:24 53:15	111:12,15	116:18	sorry 25:15 30:6
53:17 61:25 62:2	sentences 32:16	side 26:21 35:2	52:16,18 74:19
66:9,12,16 69:4,15	54:14 63:13 105:4	41:25 97:9 117:3	78:5,9 80:11 85:4
80:23 86:6 92:16		1014	

[sorry - swaine] Page 22

94:23 100:11	stated 55:10 56:14	strike 22:19 33:18	superior 125:1
sorts 77:14	121:25	86:25	supply 34:25 35:7
	statement 25:7		35:21 76:25
<b>sought</b> 56:3 <b>sounds</b> 42:17	34:20 35:9 120:22	strongly 41:15 structure 113:10	
			<b>support</b> 71:10
south 4:5 6:10	126:13,14 127:19	study 24:5 25:9	110:13
spaeder 5:15	127:19	98:1	sure 18:2 19:20
11:13	states 1:1 7:2,3,4	stuff 51:2 59:3	22:13 30:5 39:23
spears 3:9 12:3,3	10:18 12:6 24:23	subcomponents	40:6 64:9 65:7
specialist 7:6	27:8,20 58:13	68:7	67:10 70:2 71:7
specific 39:16 40:9	66:19 75:2 94:7	subject 16:17 19:9	88:20 105:16,22
42:7 43:1 45:10	97:16 116:5	20:18 79:4 100:1	105:23,25 106:8
86:11 100:24	statistical 26:15	submitted 100:20	106:12
104:8 114:9,9	26:24	subscribed 126:10	<b>surprise</b> 95:7,10
119:10 120:25	status 50:9 56:23	127:14 128:21	survey 25:25 26:1
specifically 16:14	56:25 57:2 58:8	subsequent 85:22	26:5,7 28:3 31:10
28:17 29:14 30:22	59:6 61:16,19	substance 26:21	32:18 34:12 35:9
33:10 56:22 65:20	65:18,20,21,22	38:25 67:23 90:18	35:12 36:13,20
68:5 73:13 105:18	66:6,15 81:2,7,12	114:14	38:12,15 39:1
112:9	81:16 86:1 108:2	substances 33:22	89:24 90:8 91:11
specifying 106:1	108:6 116:17	34:14 36:16 48:5	93:10,19 94:3,8
speculation 107:8	121:12 122:8	65:25 72:5,10	95:2,13,21 101:3,8
112:5 114:18	stenographic	74:2,5 75:4 77:1	101:12 103:1
115:4,16	108:20	83:11 90:25 98:12	104:3 105:14
spoke 47:14	step 68:10	substantially	114:14,15,25
springfield 3:11	<b>stephens</b> 4:13 13:9	42:14	115:10,14 116:6
staff 96:5 100:8,14	13:9	sufficient 41:24	surveys 27:11 35:6
109:25	<b>stop</b> 119:25	55:9	35:17 39:6 97:10
stakeholder 83:6	stopping 73:1	sufficiently 37:25	suspicious 29:18
stakeholders	stores 101:10,11	38:8	29:23 30:12 32:20
24:25 28:2,5 83:9	straightforward	suggesting 68:18	33:4 37:24 39:17
87:11	37:25 38:9	suite 3:16,21 4:10	39:18 40:9,10
stamp 65:13	strait 1:18 2:1 8:2	5:16 125:2	42:8,13 45:10,19
stamped 8:16	8:9 10:15 12:10	summarizing	50:2 54:8 58:15
standards 24:24	12:10 13:16,25	45:13	59:16 62:4,19
start 109:5 112:22	70:13,19 121:5	summary 24:22	66:22 72:14,18,23
starting 92:16	123:1 125:8 126:4	48:18 65:18 77:23	72:24 82:6 86:13
105:6 109:17	126:9 127:4,13	78:6,7 97:5	87:14 88:10,24
starts 100:23	128:20	107:24 108:1	89:6 100:21
state 11:5 12:13	street 2:6 3:6 4:5	109:11	108:11
111:2,4 126:10	5:4,10,16 6:5,10	summit 1:12	swaine 7:5 12:22
127:15	6:22 10:23		12:22

[swear - tucker] Page 23

12.14	4 alamba 12 22	4h:- -: 110 00	4:41ad 15:00	
swear 13:14	telephone 12:23	thinking 110:20	titled 15:22	
sworn 13:17 124:6	tell 13:17 40:17	112:10	today 11:1 14:1	
126:10,13 127:14	tellis 3:18	third 62:21 63:8	15:17 16:8,19	
127:18 128:21	tends 77:3	64:6 65:1 83:3	50:8,23 51:10,13	
systems 45:18	tense 62:9	88:12	63:5,6 69:4 72:8	
72:19,24	tenth 6:5	thirds 34:6 91:23	78:17 82:12 108:8	
t	terms 42:22 43:11	thirty 125:18	109:13 113:6	
t 5:21 8:1,1	77:4 79:19 99:9	thornburg 6:10	114:2	
table 38:22 47:22	110:20	12:15	today's 15:5 53:7	
47:24 66:4 89:10	testified 13:19	thought 55:9	80:16 85:10	
89:18,22,25 90:4	92:24 99:7	91:17	122:25	
91:9	<b>testify</b> 16:19	thoughts 105:9	told 34:22 39:14	
take 10:12 17:14	testifying 16:8,9	three 63:13 78:1	105:13	
21:5 33:14 35:8	18:10	86:17 108:4,5	top 101:19 105:4	
51:18 75:7 83:23	testimony 8:14	123:3	topic 15:22 16:20	
taken 10:15 24:14	18:5 19:13 52:14	threshold 40:20	120:2,12	
51:25 57:3 65:17	52:22 53:2,7	40:22	total 48:9 75:23	
70:8 80:1 109:2	55:11 57:15 75:19	thresholds 33:21	90:1 91:16 123:2	
112:19 124:3,7,13	78:17 84:8 85:10	34:13,24 35:3,7,20	track 62:16,20	
takes 23:2 60:13	89:15 100:17	36:6,15 39:15	63:7 64:20 68:19	
67:14 68:10,13,14	117:13 122:25	40:8 45:9	trade 105:18	
78:1	124:4,6,10 126:6,7	tiffany 3:14 11:21	117:17	
talk 14:8 50:18	127:6,9,12	70:21	training 54:10	
120:3,13	text 37:24	time 14:5,10 20:21	77:14 89:7	
talked 29:11 45:8	thank 14:1 68:9	21:21 24:13,17	transcribed 126:7	
talking 34:22 72:8	70:14,16 89:14	28:21 37:12 38:3	transcript 125:11	
90:17 98:16,22	107:18 122:16	42:10,24 43:25	125:12 126:5,12	
· ·	thanks 47:10	49:7 51:24 52:5	127:5,11,17	
119:2,3,7 talks 59:12 63:14	106:18	54:25 57:5 60:17	transcription	
82:21 83:3 107:25	<b>theme</b> 106:11	61:2 63:4 70:7,11	124:8	
122:8	thing 90:3 115:6	70:14,15 82:11,19	transpired 93:7	
	things 20:2 72:22	86:24 87:2 90:12	treatment 40:25	
targeted 105:18 tasked 100:10	79:25 86:15	91:1 98:14 100:17	<b>tried</b> 99:12	
	117:17	103:9 109:1,7	true 22:16 46:23	
team 21:19,24 55:21 56:18 85:19	think 20:7 26:20	112:15,18,24	49:6 54:25 124:9	
	32:5 34:23 36:3	118:7,13,20 120:1	<b>truth</b> 13:18,18,19	
100:10	38:10,23 43:6,16	121:8 122:19,23	try 14:8 20:1	
technical 71:3	59:2 64:7 70:3	timely 21:1	trying 64:7 93:15	
teleconference 4:4	76:6,22 80:11	times 19:23	105:24	
4:8,14,18 5:3,22	84:4 91:3,5 106:9	title 52:20	tucker 4:9 13:2	
6:9,15,20 7:5	106:16 108:16		_	

## [tuckerellis.com - wicht]

tuckerellis.com	underway 15:8	13:13,21 24:11,15	walmart 4:12
4:11	unified 50:2,7	51:21 52:1 70:5,9	want 30:21 34:1
turn 10:9 32:11	unintended 42:4	108:23 109:3	38:20 43:5 60:6
34:5 47:21 58:11	unit 10:14 51:23	112:16,20 122:17	64:13 71:1 75:17
61:25	52:3 108:25 109:5	122:21	80:2 81:23 89:10
turning 24:20	112:22	videotaped 1:18	92:13 101:11
44:14 46:5 53:9	united 1:1 7:2,3,4	2:1 8:9	105:23 106:8
two 17:19 32:16	10:18 12:5 75:2	view 36:12 58:3	107:11 108:17
34:6 47:14 54:13	units 123:2	views 18:6	110:3 111:19
63:13 80:12 88:15	unusual 42:13,15	virginia 3:11	116:4 121:17
88:25 91:20,23	42:19 43:1	vocal 99:6	wanted 31:5 38:13
105:3 106:5 120:8	<b>update</b> 57:3 61:17	volumes 76:25	43:7 56:7 111:8
<b>type</b> 81:19	64:1,24 67:25	vs 1:10	117:18,23 121:1
types 29:13 35:3	68:16 81:2,7	W	warning 83:10
41:1,7 56:15	85:20,22 86:8	w 3:16	washington 1:19
typical 21:15	87:24	wacker 3:21 4:19	2:7 3:7 5:10,17
typically 22:7	<b>usdoj.gov</b> 3:8,12	waites 3:4 12:8,8	6:5 10:23
u	use 40:19 71:14	19:16 22:12 25:24	way 20:15 21:15
<b>u.s.</b> 3:3,5,9 8:15	uses 74:2	30:19 33:24 42:20	34:7 36:2 76:12
uh 32:14 73:16	V	43:3 48:17 49:1	80:12 93:15 99:13
ultimately 34:17	v 1:8,12 125:6	49:14 50:11 51:14	110:19 115:1
35:21	126:3 127:3	51:20 57:14 59:17	ways 37:21 84:15
unclear 35:10,13	vague 22:12 25:24	60:20 65:3 69:8	118:3
undergoing 66:23	33:24 74:13 96:25	73:2 74:13 75:9	wc.com 5:11,12
underneath 56:18	114:17	75:11 76:15 77:18	we've 40:23 51:2
understand 16:4	values 71:20	78:23,25 79:7,16	72:8 91:5 106:10
16:17 20:1 31:1	variables 39:18	80:9 95:23 96:6	109:12 120:23
51:7 54:22 99:12	40:10	96:12,22 99:17	web 27:10 32:9
110:12	various 83:7 111:4	102:6 106:21	65:17 66:15 77:12
understanding	<b>vastly</b> 41:13	107:7 111:13	83:2 97:10 107:25 109:11 122:9
28:9,25 30:14	<b>venue</b> 84:24	112:4 113:11,17	weitz 3:15 11:20
48:4 58:6 60:22	verbal 31:2	113:24 114:17	11:21
60:24 66:1 81:25	veritext 10:25	115:3,15 117:12	weitzlux.com 3:18
103:23 112:1	11:2 123:3 125:1	118:16,23 119:23	went 42:10 56:1
120:11	125:7 128:1	120:7,23 122:4	west 3:21 4:19
understood 38:4	veritext.com.	125:5	whispering 10:7
38:13 40:16 55:11	125:17	<b>waived</b> 125:19	white 63:20 64:11
55:13 89:17	versus 76:12	wal 12:21 13:10	wholesale 29:23
undertaken 24:5	video 10:11,14	walk 45:6	wicht 5:8 11:10,10
undertaking 57:19		<b>wallace</b> 4:4 13:4,4	, , , , , , , , , , , , , , , , , , ,
	10:3 11:1 12:12		

#### [widely - zuckerman.com]

Г	I	
<b>widely</b> 46:12	<b>worked</b> 106:10	
<b>williams</b> 2:5 5:9	<b>working</b> 18:8,10	
10:22 11:8,10	21:25 41:18 84:6	
<b>willing</b> 42:6 101:8	87:10 94:20 98:13	
115:9	works 56:20	
wisconsin 6:16	<b>worth</b> 106:14	
<b>wishes</b> 73:18	<b>wrap</b> 120:8	
witness 3:3 13:14	writing 31:2 43:8	
19:21 25:25 30:21	55:14,18,24 56:7	
34:1 36:1 42:21	written 30:17 32:3	
43:4 48:18 49:16	32:8 42:25 43:1	
50:16 51:16 53:4	43:23,24 46:10,16	
57:16 59:19 60:21	48:12,13 49:17	
65:5 69:10 70:16	50:3,25 51:11	
74:10 75:13 76:17	57:12 58:4,22	
79:9,17 91:22	59:15 61:6 62:12	
92:10 93:12,23	62:13 69:18 82:10	
94:10 95:4,9 96:1	83:17,21 84:3	
96:9,15 97:1 98:4	121:25	
98:10 99:3,19	wrong 74:22	
102:7,20 103:15	wrote 64:2 81:15	
103:23 104:11	y	
105:1 106:24		
107:9 110:17,19	yeah 11:23 38:20	
112:8 113:12,18	44:16 47:17 49:4	
113:25 114:19	65:5 69:10 90:13	
115:5,17 117:14	112:6,8 117:23	
118:11,17,24	119:9	
120:13 122:6	year 62:21 63:8	
124:4,6,10 125:8	64:6 65:2 67:2	
125:11 126:1,4,11	68:20,24 81:5,6	
127:1,4,15	yearly 54:10 89:7	
witnesses 18:5	years 14:21 17:12	
19:12 99:7	17:15,20 38:4	
witness' 125:14	60:3 69:16	
work 20:7,8,16	<b>yep</b> 73:20	
51:4 83:4 88:14	Z	
88:21 106:12	zuckerman 5:15	
113:22 116:12 11:12		
117:1	zuckerman.com	
	5:18	

# Federal Rules of Civil Procedure Rule 30

- (e) Review By the Witness; Changes.
- (1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:
- (A) to review the transcript or recording; and
- (B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.
- (2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES

ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY.

THE ABOVE RULES ARE CURRENT AS OF APRIL 1,

2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES

OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

## VERITEXT LEGAL SOLUTIONS COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

Veritext Legal Solutions is committed to maintaining the confidentiality of client and witness information, in accordance with the regulations promulgated under the Health Insurance Portability and Accountability Act (HIPAA), as amended with respect to protected health information and the Gramm-Leach-Bliley Act, as amended, with respect to Personally Identifiable Information (PII). Physical transcripts and exhibits are managed under strict facility and personnel access controls. Electronic files of documents are stored in encrypted form and are transmitted in an encrypted fashion to authenticated parties who are permitted to access the material. Our data is hosted in a Tier 4 SSAE 16 certified facility.

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